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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD.,	Consolidated Civil Action No. 20-10172 (MCA)(MAH)
Plaintiffs,	CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER
v.	
CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC,	
Defendants.	

OPENING EXPERT REPORT OF DR. DAVID LEWIS, PH.D. AS TO DEFENDANT CIPLA LTD.

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I. Background and Qualifications

1. My name is David Lewis, and I am Director of Oz-UK Ltd. ("Oz-UK") and 3DI Solutions Ltd. ("3DI Solutions"). I have held those positions since July 2015 and April 2008, respectively. Oz-UK and 3DI Solutions are pharmaceutical consulting companies that support industry participants in their efforts to research and develop inhalation products, including metered dose and dry powder inhalers with dose counters or dose indicators. At Oz-UK and 3DI Solutions, I frequently provide companies with advice regarding the formulation, packaging, and design of such devices.

2. I hold three degrees from the University of Essex, including a bachelor's degree with honors in physics (1989), a master's degree in chemistry (1991), and doctorate in chemistry (1994). My master's research focused on the spray characteristics of pressurized packages (i.e., canisters) containing chlorofluorocarbon and hydrocarbon propellant formulations.

3. I have more than twenty-five years' experience working in the inhalation device industry. Between August 2008 and August 2020, I was Director of Aerosol Science at Chiesi Ltd., UK ("Chiesi"). Chiesi is an international pharmaceutical company that researches and develops drug products and devices. While there, I led Chiesi's research and development of its Atimos®, Clenil®, Foster®/FostAir®, and Trimbow® inhalation products. My responsibilities included overseeing research and development of both the formulations and their packaging, including the design of the inhalers for those devices. I also oversaw testing of the finished products, including any dose counters or dose indicators. In addition to my work on specific products, I founded Chiesi's U.K. Research Center in Chippenham, United Kingdom, as the center for excellence for Chiesi's metered dose inhaler and dry powder products.

4. Between May 1996 and May 2008, I was Head of Hydrofluoroalkane ("HFA") Programmes at Vectura Ltd. ("Vectura"). Today, Vectura is a British pharmaceutical company

that specializes in researching and developing dry powder and metered dose inhalers. In 1997, Vectura spun off from the University of Bath as a vehicle for commercializing technologies developed at the university. I was one of the key managers involved in overseeing that transition.

5. On numerous occasions, I have provided advice to pharmaceutical companies and research universities regarding the design of metered dose inhalers and/or dose counters, including, among others, Chiesi Farmaceutici S.p.A, Copley Scientific Ltd., Oxford Lasers Ltd., King's College London, Loughborough University, Monash University, University of Bristol, University of Parma, and University of Sydney. Because of my reputation, companies and universities seek my services to assist them in solving problems that their own scientists and engineers cannot.

6. During my career, I have authored more than 130 publications involving inhalation technologies. Representative publications include, among others, Farkas et al., *Experimental and Computational Study of the Effect of Breath-Actuated Mechanism Built in the NEXThaler® Dry Powder Inhaler*, 533 Int'l J Pharm. 225 (2017); Gavtash et al., *Transient Flashing Propellant Flow Models to Predict Internal Flow Characteristics, Spray Velocity, and Aerosol Droplet Size of a pMDI*, 52 Aerosol Sci. & Tech. 494 (2017); Mason-Smith et al., *Insights into Spray Development from Metered-Dose Inhalers through Quantitative X-Ray Radiography*, 33 Pharm. Res. 1249 (2016); Chen et al., *High-Speed Laser Image Analysis of Plume Angles for Pressurized Metered Dose Inhalers: The Effect of Nozzle Geometry*, 18 AAPS PharmSciTech. 782 (2016); Chen et al., *The Influence of Actuator Materials and Nozzle Designs on Electrostatic Charge of Pressurised Metered Dose Inhaler (pMDI) Formulations*, 31 Pharm. Res. 1325 (2014); and Lewis, *Metered Dose Inhalers: Actuators Old and New*, 4 Expert Opinion

on Drug Delivery 235 (2007), the last of which I understand the parties to have cited in this litigation. I also hold more than 30 patents covering inhalation technologies.

7. I have served as a referee for *Aerosol Science and Technology*, which is the official journal of the American Association for Aerosol Research, and I have been asked to serve as an editor or referee for numerous other high-impact journals.

8. My curriculum vitae describing my professional experience, educational credentials, and publications are attached as Exhibit A to this report.

9. Based on my experience and qualifications, I consider myself to be an expert in inhalation device technology, including the design of metered dose inhalers and dose counters.

10. In forming my opinions, I have considered the materials cited in this report. I have also considered the Asserted Patents (as defined below), the Asserted Patents' file histories, Defendants' non-infringement contentions, and the materials cited in those contentions, as well as my education, training, and experience. In addition to the opinions and bases set forth in this report, my testimony may include responses to facts, arguments, allegations, or references raised by Defendants or their experts in this litigation. I reserve the right to supplement my opinions if additional information is provided to me or if additional research leads me to conclude that supplementation is necessary.

11. Counsel for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, "Teva") have engaged me in this litigation. I am being compensated for my time at a rate of £300.00 GBP per hour, plus expenses. My compensation is not contingent upon the outcome of this litigation.

12. In the previous four years, I have testified by deposition or at trial in European cases involving Chiesi's Atimos®, Clenil®, Foster®/FostAir®, and Trimbow® products.

13. If asked, I will be prepared to present a basic tutorial to explain the terms and concepts related to the opinions set forth in my expert report, as well as to provide further background on inhalation aerosol drug products and dose counters, the state of the art, the level of skill in the art, and the patents at issue. That tutorial may include demonstrative exhibits and models, including models generated by software.

14. Furthermore, and as noted throughout this report, I will be prepared to present a physical demonstration of the limitations at issue in this case using Teva's Qvar® HFA or ProAir® HFA products, Defendants' Abbreviated New Drug Application ("ANDA") Products, other inhalers or dose counters, or representations of those products. This demonstration may include demonstrative exhibits and models, including models generated by software.

15. In addition to the opinions and bases set forth in this report, I may supplement my opinions—including in the event Defendants amend or supplement their ANDAs or make changes to their proposed generic products or the processes for manufacturing them—and my testimony may include responses to facts, arguments, allegations, or references raised by Defendants or their experts.

II. The Asserted Patents

16. I have been informed that Teva has asserted the following patents and claims against Defendants Cipla Ltd. ("Cipla") and Aurobindo Pharma, LLC, Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo"):

a. U.S. Patent No. 9,463,289 (the "'289 Patent"), Claims 1-8;

b. U.S. Patent No. 9,808,587 (the "'587 Patent"), Claims 1-8, 11-22;

c. U.S. Patent No. 10,086,156 (the "'156 Patent"), Claims 1, 9, 11-13; and

d. U.S. Patent No. 10,561,808 (the "'808 Patent"), Claims 1, 27-28

(collectively, the "Asserted Patents" and "Asserted Claims").

17. Each of the Asserted Patents claims priority to U.S. Provisional Patent Application Nos. 61/345,763 (the "'763 Provisional Application"), filed May 18, 2010, and 61/417,659 (the "'659 Provisional Application"), filed November 29, 2010. The Asserted Patents also name the following individuals as inventors: Declan Walsh, Derek Fenlon, Simon Kaar, Jan Geert Hazenberg, Daniel Buck, Paul Clancy, Robert Charles Uschold, and Jeffrey A. Karg. I have been informed that Mr. Walsh and Mr. Karg have been deposed in this case, and I have reviewed their deposition transcripts.

18. I discuss the specific limitations of the Asserted Claims in greater detail below, but as a general matter, the Asserted Claims relate to metered dose inhalers or dose counters with specific combinations of components and features. As I explain in the Sections on objective indicia of non-obviousness, the novel aspects of the claims address multiple problems with prior art devices, including the need for inhalers with accurate, reliable, and robust dose counters that did not sacrifice functionality, manufacturability, maintainability, or human factors (such as, for example, aesthetics or ergonomics), to achieve those goals.

III. Cipla's ANDA Product

19. I have been informed that Cipla has filed Abbreviated New Drug Application ("ANDA") No. 214434 ("Cipla's ANDA"), which seeks the U.S. Food and Drug Administration's ("FDA's") approval to market a generic version of Qvar® HFA. I have been informed that Cipla's Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg and 80 mcg drug product ("Cipla's ANDA Product") is the subject of that application.

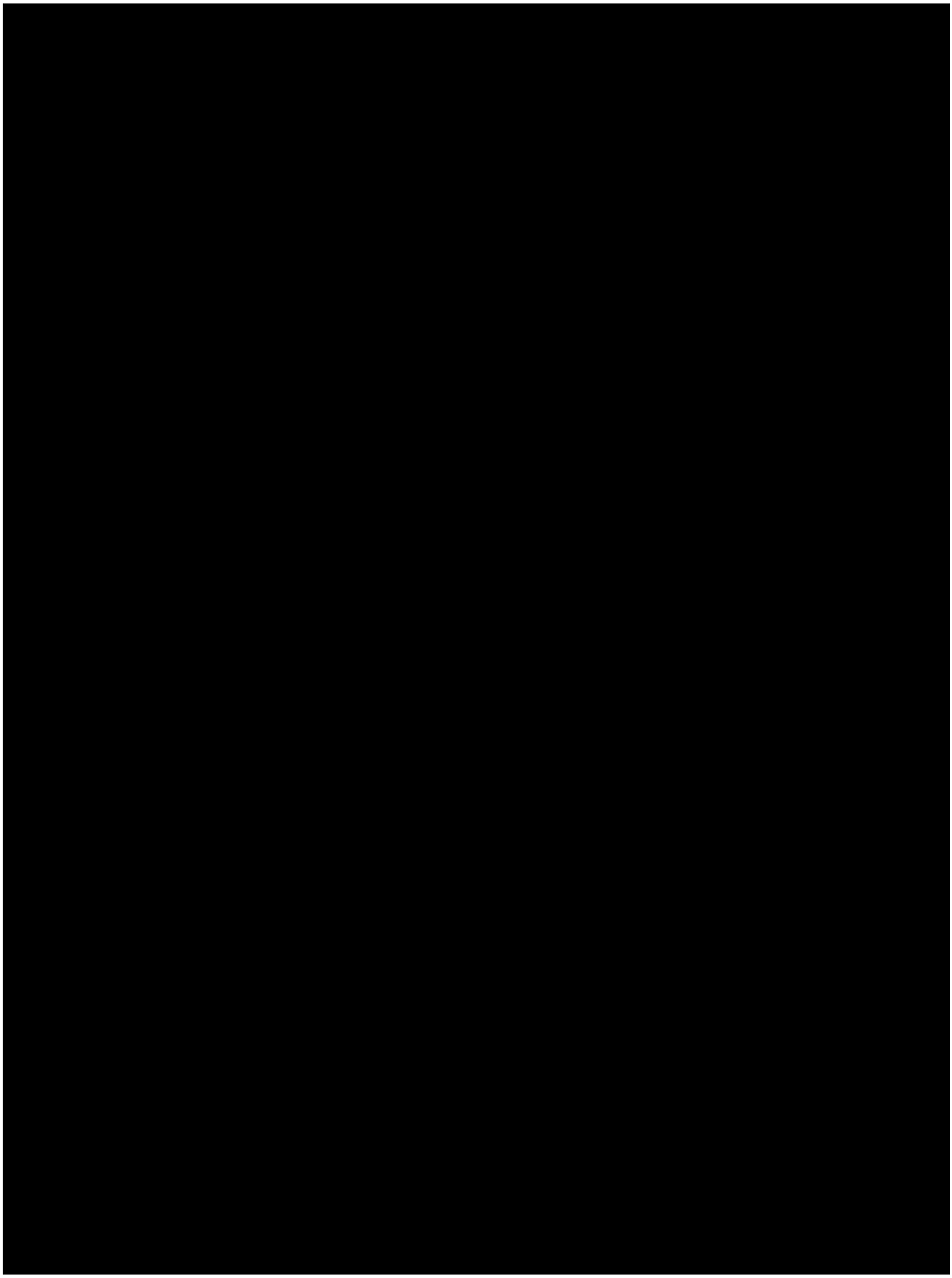
20. For this matter, I have inspected samples of Cipla's ANDA Product and reviewed relevant portions of Cipla's ANDA and related materials. *See, e.g.*, Cipla Samples;[1] CIPLA-

[1] I refer to the 40 mg and 80 mg samples provided by Cipla collectively as the "Cipla

BDI_0000635 (Cover Letter); CIPLA-BDI_0155972 (Proposed Labeling); CIPLA-BDI_0003995; CIPLA-BDI_0004411 (Pharmaceutical Development); CIPLA-BDI_0010839 (Container Closure System); CIPLA-BDI_0156579; (Design Diagrams); CIPLA-BDI_0000979, at -979-1024; CIPLA-BDI_0063192 (Threshold Analyses). I have also reviewed the deposition testimony of Cipla's witnesses, including Cipla's corporate representative, and documents relating to the research and development of Cipla's ANDA Product and the inhaler and dose counter used in that product. I cite these documents throughout my report.

21. [redacted]

Samples" in my report.

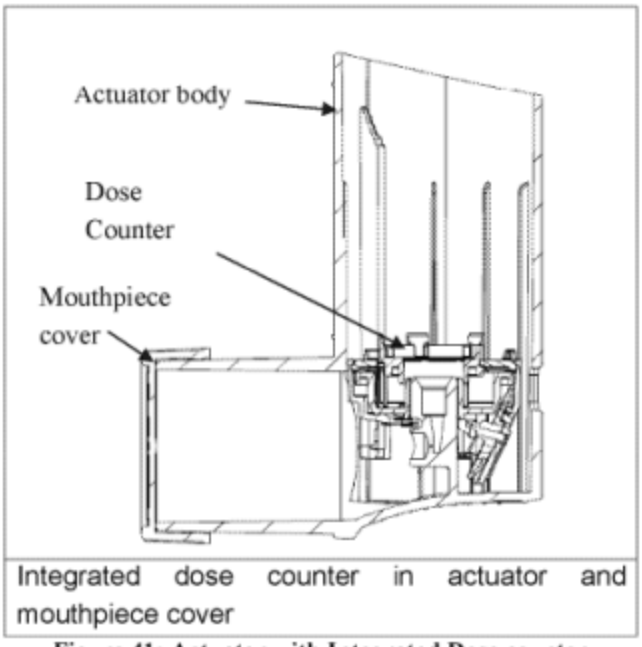


22. Cipla's ANDA contains the following design diagram, which depicts a canister housing (which Cipla's ANDA refers to as an "actuator") and dose counter used in Cipla's ANDA Product.

C. Demonstration of *in vitro* robustness, accuracy and functionality of Actuator having Dose counter.

The developed actuator with integrated counter for the drug product [redacted] displacement driven and is designed to advance when the patient depresses and releases the inhaler. This will allow the patient to track the labelled number of actuations remaining in their inhaler.

The operation of the dose counter is governed by the distance that the metering valve is displaced during actuation. The dose counter is integrated into the actuator. The dose counter is firmly clipped into the actuator to prevent its removal. A diagram of the actuator with integrated dose counter and its components is presented in below figure.

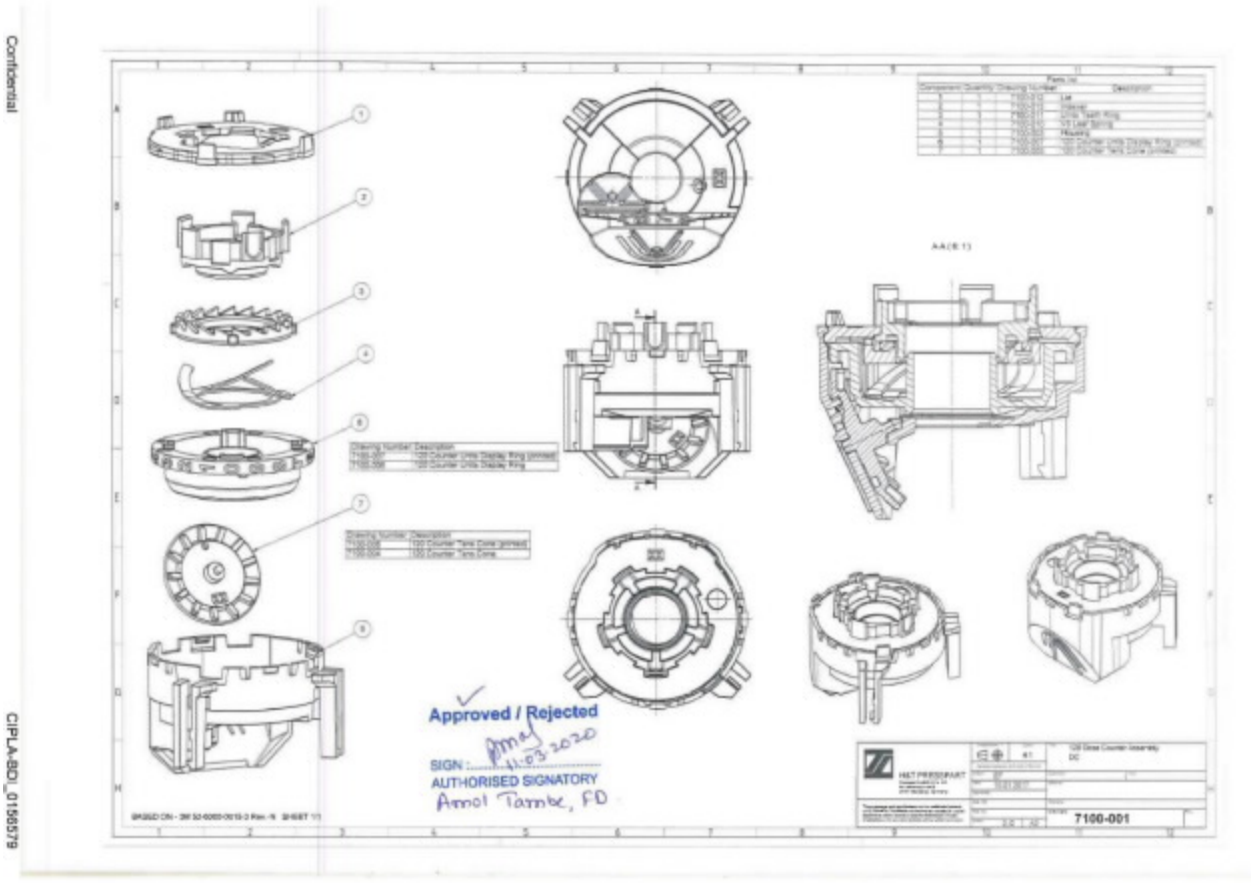


Integrated dose counter in actuator and mouthpiece cover

Figure 41: Actuator with Integrated Dose counter

CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report).

23. I have been informed that Cipla has represented the following design drawing accurately represents the dose counter in Cipla's ANDA Product.



CIPLA-BDI_0156579 (Design Drawing); Rote Dep. Tr. 31:6-22. As set forth in the drawing above, Cipla's dose counter comprises at least the following elements: (1) a "Lid," (2) "Indexer," (3) "Units Teeth Ring," (4) "V5 Leaf Spring," (5) "Housing," (6) "120 Counter Unites Display Ring (printed)," and (7) "120 Counter Tens Cone (printed)."

24. The following design diagrams also depict the assembled dose counter and canister housings used in Cipla's ANDA Product.

See, e.g., CIPLA-BDI_0803837-38 (Design Drawings); Rote Dep. Tr. 47:1-48:8, 60:12-61:6.

25. As discussed throughout, these materials support my opinions that Cipla's ANDA Product satisfies every limitation of the Asserted Claims.

26. In addition to reviewing materials describing Cipla's ANDA Product, I also conducted experiments involving Cipla's ANDA Product, which are described below and in Exhibits B and C to this report. Such experiments included comparisons of Cipla's ANDA Product with and without the inner wall canister support formations (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs"), and a force-displacement analysis of Cipla ANDA Product, measuring the amount of force and distance needed to cause Cipla's ANDA Product to fire and count.

27. Based on my review of Cipla's documents and samples, and the other materials cited in my report, I conclude that for the purposes of my opinions, any differences between the 40 mcg and 80 mcg versions of Cipla's ANDA Product are irrelevant. I do not understand Cipla to contend otherwise and, indeed, Cipla refers to "the Cipla ANDA Product" throughout its contentions. *See* Cipla Non-Infringement Contentions.

IV. Cipla's DMFs

28. As noted in the Section above, Cipla's ANDA references a number of DMFs in connection with its inhaler and dose counter, including [redacted] I have reviewed [redacted]

33. These materials further corroborate my opinions that Cipla's ANDA Product satisfies every limitation of the Asserted Claims.

V. The Person of Ordinary Skill in the Art

34. I have been asked to provide a definition of "a person of ordinary skill in the art" ("POSA") to whom the inventions disclosed and claimed in the Asserted Patents were directed, as of the relevant priority dates.

35. I have been informed that Plaintiffs contend that the Asserted Claims of the '289, '587, '156, and '808 Patents are entitled to a priority date of no later than May 18, 2009; alternatively November 5, 2009; alternatively, no later than December 2, 2009; alternatively, no later than March 16, 2010 (in the case of the '808 Patent only); alternatively, no later than May

18, 2010, the date on which the '763 Provisional Application was filed; alternatively, no later than November 29, 2010, the date on which the '659 Provisional Application was filed; and alternatively, no later than May 18, 2011, the date on which U.S. Patent Application No. 13/110,532 was filed. If asked, I will address the issue of the priority date to which the claims asserted in this case are entitled in a subsequent report.

36. I have applied these dates in my analysis. For purposes of my opinions set forth in this report, it does not matter which date between May 18, 2009, and May 18, 2011, is the priority date. My opinions would remain the same based on any priority date within that range. I reserve the right to supplement my opinions in the event that the parties present additional arguments or evidence (including references published after May 18, 2009) relevant to this issue.

37. I have been informed that a POSA is a hypothetical person who may possess the skills, education, and experience of multiple individuals working together as a team. I have been informed that factors for determining the level of ordinary skill in the art may include one or more of the following: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the relevant technology; and (6) the educational level of workers active in the field.

38. I have considered these factors in my analysis. For example, I note that several of the named inventors held master's degrees in mechanical engineering as of the priority dates and had worked in the field for a number of years. *See, e.g.*, Walsh Tr. 24:7-28:18; Karg Tr. 11:1-37:7. I further note that, based on my experience in inhaler and dose counter design, individuals working in the field of the invention as of the priority date included individuals with bachelor's or advanced degrees in a variety of disciplines, including mechanical or design engineering and

related fields. Such individuals also included (or would have at least had access to) physicians with experience treating patients with inhalation and aerosol devices.

39. In my opinion, the POSA for the Asserted Claims as of the priority dates would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included one or more individuals with master's degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor's degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. The team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices.

40. I have been informed that Cipla contends that as of May 18, 2010, the POSA for the Asserted Claims would be a person with a bachelor's degree in pharmaceutical science or a related discipline, and at least 2-3 years of product development experience with design and manufacture of metered dose inhalers. Alternatively, Cipla contends that the POSA would have a master's degree or Ph.D. in pharmaceutical science, mechanical or medical device engineering, or a related discipline, and at least 1-2 years of product development experience with metered dose inhalers. Cipla also contends that a POSA may have also worked as part of a multi-disciplinary team of scientists in pursuit of developing a pharmaceutical product and drawn upon not only his or her own skills, but also consulted with others of the team having specialized skills.

41. It is unclear to me how Cipla derived that definition of the POSA, and I disagree with it to the extent that it conflicts with my own. Nevertheless, my opinions would not change if I were to assume, contrary to my opinion, that Cipla's definition is correct.

42. I reserve the right to supplement my opinions in the event that the parties present additional argument or evidence relevant to this issue.

VI. Claim Construction

43. I have been informed that claim construction refers to the process in which the Court determines the legal meaning of a patent's claims. I have been informed that a patent's claims should be construed according to their ordinary and customary meaning in view of the patent's specification and prosecution history, unless the patent defines a claim term, in which case that definition should be applied.

44. I have been informed that the parties have agreed to the following claim constructions. I have applied those constructions in forming my opinions.

No.	Term	Agreed-Upon Construction
1	"canister housing" '289 patent, claim 1 '587 patent, claims 1, 12, and 13	"the portion of the inhaler body that is arranged to retain a medicament canister"
2	"inside surface" '289 patent, claim 4 '587 patent, claims 4 and 17	"an interior surface"
3	"body" '156 patent, claim 1	"the body of the inhaler"
4	"associated with" '156 patent, claim 1	"related to"

5	"canister support formation" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 11-13, 15	"a formation arranged to reduce canister rocking"
6	"actuator" '156 Patent, claims 1, 2, 12	"A structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component."
7	"actuator pawl arranged to engage with a first tooth of the ratchet wheel" '156 Patent, claim 1	"a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel."
8	"wall surfaces separating the canister receiving portion and the counter chamber" '156 Patent, claim 1	"wall surfaces of the inhaler body which are substantially perpendicular to the direction of canister movement and which divide the canister-receiving portion and counter chamber"
9	"regulator" '808 Patent, claims 1, 27	"a structure of the dose counter that modulates motion of the counter display"
10	"regulate motion of the counter display" '808 Patent, claim 1	"modulate motion of the counter display"
11	"ratchet wheel" '156 Patent, claims 1, 9, 12	"a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl"
12	"first direction" '808 Patent: 1	"single direction at a time"
13	"main surface of the inner wall" '289 Patent, claim 1 '587 Patent, claim 1, 12, 13	"inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel

		medicament"
14	"inner wall through which a portion of the actuation member extends" '289 Patent, claim 3 '587 Patent, claims 3, 13	"an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament"
15	"inner wall" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 12, 13, 15, 21, 22	"an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body"
26	"protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" '587 patent, claim 1	"guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter"

Joint Claim Construction Chart 3-5.

45. I have been informed that the parties dispute the meaning of the following claim terms and have proposed competing constructions. I have been informed that the Court has yet to rule on these disputes. Accordingly, I have applied both parties' constructions in forming my opinions. In my opinion, and as explained in this report, Defendants both infringe each of the Asserted Claims under either side's proposed constructions.

No.	**Term**	**Plaintiffs' Construction**	**Defendants' Construction**
1	"actuation member" '289 Patent, claims 1, 3 '587 Patent, claims 1, 3, 11, 12, 13	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter's actuator that	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"

No.	Term	Plaintiffs' Construction	Defendants' Construction
	'156 patent, claims 12	transmits motion from the canister to the actuator"	
2	"[lying or lie] in a common plane coincident with the longitudinal axis X" '289 Patent, claim 1 '587 Patent, claims 1, 12, 21, 22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.	"aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"
3	"positioned at opposite ends of the inside surface of the main body to face each other" '289 Patent, claim 7 '587 Patent, claims 7, 18	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other"	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"
4	"step[(s)] formed thereon" '289 Patent, claims 5, 8 '587 Patent, claims: 5, 8, 16, 19	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a location of changing width dimension thereon"	"A stepwise increase in the extent to which the support rail extends inwardly"
5	"first reset position" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a position of the actuator in which the actuator pawl is brought into engagement	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"

No.	Term	Plaintiffs' Construction	Defendants' Construction
		with the first tooth of the ratchet wheel and which is before the canister fire configuration"	
6	"canister fire sequence" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"	"process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel."
7	"canister fire configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter in which the medicament canister fires medicament"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"
8	"count configuration" '156 Patent, claims 1, 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter whereby the dosage indicator has	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"

No.	Term	Plaintiffs' Construction	Defendants' Construction
		indicated a count"	
9	"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister" '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"
10	"the body" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "inhaler body" - '156 Patent, 22:64, 67 "dose counter body" - '156 Patent, 22:66	This term is indefinite.
11	"counter display arranged to indicate dosage information" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a component of the dose counter that displays information regarding the number of doses remaining"	"structure displaying the number of doses remaining"
12	"first station" '808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a first region"	"first structure on which the counter is located"
13	"second station"	Plain and ordinary meaning	"second structure, separate

No.	Term	Plaintiffs' Construction	Defendants' Construction
	'808 Patent, claim 1	in view of the claims, specification, and prosecution history. "a second region"	from the first structure, to which the counter display is moved"
14	"aperture" '289 Patent, claim 3 '587 Patent, claims 3, 13, 20-22	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "an opening or open space: hole"	"hole"
15	"separate counter chamber" '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a separate chamber of the inhaler in which the dose counter is located"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"
16	"count pawl" '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"

See Joint Claim Construction Chart 6-10.

46. I reserve the right to supplement my opinions in the event that the Court construes these terms or the parties present additional arguments or evidence relevant to these issues.

VII. Summary of Opinions

47. The following paragraphs summarize some of my opinions in this matter at a high

level. This summary is not meant to limit the opinions expressed below in greater detail, but instead to provide a general overview of the subject matter of my testimony.

48. I have been asked to provide an opinion regarding whether Cipla infringes the Asserted Claims. As part of that analysis, I have been asked to analyze whether Cipla's ANDA Product satisfies each of the Asserted Claims literally and/or under the doctrine of equivalents. I have also been asked to provide opinions regarding whether Qvar® HFA with dose counter and ProAir HFA® with dose counter are embodiments of the Asserted Claims and whether the inventions recited in the Asserted Claims are associated with certain objective indicia of non-obviousness, including long-felt, unmet need; failure of others; industry acceptance and praise; and copying.

49. In my opinion, Cipla infringes each of the Asserted Claims. As I explain below in greater detail, Cipla's ANDA Product satisfies each of the limitations of the Asserted Claims, including the limitations recited in the claims from which they depend. To the extent that Cipla's ANDA Product does not literally satisfy each of those limitations, Cipla's ANDA Product satisfies those limitations under the doctrine of equivalents both because Cipla's ANDA Product has one or more features that are insubstantially different from the limitations in question and because those features perform substantially the same function in substantially the same way to obtain the same result as those limitations.

50. In my opinion, Qvar® HFA with dose counter and ProAir® HFA with dose counter are embodiments of the Asserted Claims. Additionally, the inventions recited in the Asserted Claims, including as embodied in Qvar® HFA and ProAir® HFA are associated with various objective indicia of non-obviousness, including:

a. Long-Felt, Unmet Need: As of the priority dates, there were long-felt,

unmet needs for inhalers with dose counters having the properties of the claimed inventions, including the need for inhalers with dose counters having sufficient functionality, accuracy (including, with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors).

b. Failure of Others: As of the priority dates, others, including multiple established pharmaceutical companies, tried, but failed, to research and develop inhalers and dose counters having the properties of the claimed inventions, including the properties described above. Despite these efforts, however, only Qvar® HFA with dose counter and ProAir® with dose counter succeeded in having these properties, including the combination of those properties.

c. Industry Acceptance: As reflected in FDA's approval of Qvar® HFA with dose counter and ProAir® with dose counter, the inhalation device industry has accepted the inventions recited in the Asserted Claims. Since then, the industry has recognized Qvar® HFA with dose counter and ProAir® HFA with dose counter as leading products for their respective indications.

d. Praise: Since their approvals, the inhalation device industry has praised the inventions recited in the Asserted Claims, as embodied by Qvar® HFA with dose counter and ProAir® HFA with dose counter for having the properties described above.

e. Copying: Despite the availability of numerous alternatives, both Cipla and Aurobindo chose to copy Qvar® HFA with dose counter.

In my opinion, each of these objective indicia, alone and in combination with one or

more other objective indicia, provides evidence that the inventions recited in the Asserted Claims would not have been obvious.

VIII. Infringement

51. I have been informed that a party infringes a patent claim if it commercially makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent. I have been informed that a party also infringes a patent claim if it files with FDA an ANDA for a drug claimed in a patent or the use of which is claimed in a patent.

52. I have been informed that a party may infringe a claim literally or under the doctrine of equivalents. I have been informed that even if a party does not literally infringe a claim, it infringes the claim under the doctrine of equivalents if (1) the differences between each claim limitation and the accused equivalent are insubstantial or (2) each claim limitation and the accused equivalent performs substantially the same function in substantially the same way to obtain the same result. I have been informed that infringement under the doctrine of equivalents is assessed on a claim limitation-by-limitation basis. I have been informed that Plaintiffs bear the burden to prove infringement by a preponderance of the evidence, meaning that a factual proposition is more likely than not.

53. I have applied the above standards in forming my opinions.

A. U.S. Patent No. 9,463,289 ('289 Patent)

1. '289 Patent, Claim 1

54. In my opinion, Cipla's ANDA Product satisfies every limitation of claim 1 of the '289 Patent.

55. Claim 1 recites as follows:

1. An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,
a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

I address each limitation of this claim below.

a. "Inhaler for Metered Dose Inhalation"

56. In my opinion, Cipla's ANDA Product is an "inhaler for metered dose inhalation." *See, e.g.*, Cipla Samples; CIPLA-BDI_0000635 (Cover Letter) ("Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg and 80 mcg"); CIPLA-BDI_0155972, at -974 (Proposed Labeling) ("Inhalation Aerosol: Beclomethasone dipropionate HFA, inhalation aerosol is a pressurized, metered-dose aerosol with a dose counter intended for oral inhalation . . ."); CIPLA-BDI_0803837-38 (Design Drawings). Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla Samples. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 1.

b. "A Main Body Having a Canister Housing"

57. In my opinion, Cipla's ANDA Product comprises "a main body having a canister housing." I have been informed that the parties have agreed that the term "canister housing" should be construed to mean "the portion of the inhaler body that is arranged to retain a medicament canister." I have applied this construction in my analysis.

58. Cipla's ANDA Product comprises a medicament "canister." *See, e.g.*, Cipla

Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling); CIPLA-BDI_0156595, at -595, -597 (Photographs); CIPLA-BDI_0803837-38 (Design Drawings). Cipla's ANDA Product further comprises a "main body" (i.e., what Cipla refers to as an "actuator"). Cipla's main body has a portion which is arranged to retain a medicament canister. Below, I depict the portion of Cipla's ANDA Product that corresponds to the main body.

See, e.g., CIPLA-BDI_0156595, at -595, -597 (Photographs);[2] *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

[2] All markup added unless otherwise noted.

59. At his deposition, Cipla' corporate representative confirmed that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Rote Dep. Tr. 47:5-7 ("Q. Mr. Rote, do you recognize this as a schematic of Cipla's dose counter inside of one of the actuators that's used in Cipla's ANDA product? A. That's correct.").

60. [redacted]

61. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla Samples.

62. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 1.

c. "A Medicament Canister, Which is Moveable Relative to the Canister Housing and Retained in a Central Outlet Port of the Canister Housing Arranged to Mate with a Canister Fire Stem of the Medicament Canister"

63. In my opinion, Cipla's ANDA Product comprises "a medicament canister, which

[3] [redacted] based on my review of [redacted] there are no material differences between the Defendants' products. [redacted] IPLA-BDI_0000004 (Form 356h); Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister."

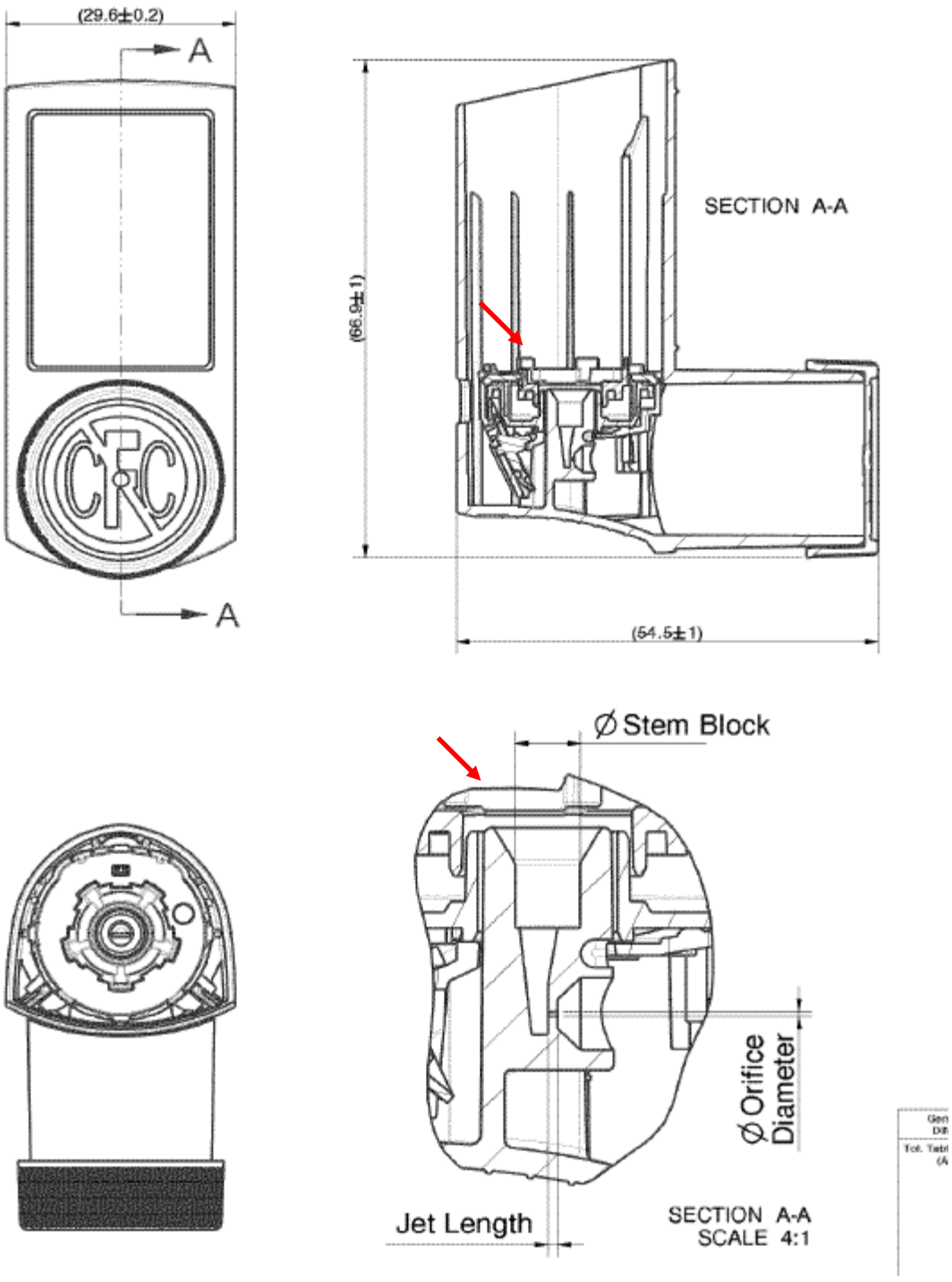
64. As discussed in the Section above, Cipla's ANDA Product comprises a medicament canister. *See, e.g.*, Cipla Samples; CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling); CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156595, at -595, -597 (Photographs); CIPLA-BDI_0803837-38 (Design Drawings).

65. Cipla's ANDA medicament canister has a stem.

See, e.g., CIPLA-BDI_0156595, at -597 (Photographs).

CIPLA-BDI_0156595, at -595 (Photographs); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

66. Cipla's medicament canister is retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister. Below, I depict the central outlet port in Cipla's canister housing, which is arranged to mate with the canister fire stem of Cipla's canister.



See, e.g., CIPLA-BDI_0803837-38 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156595, at -595, -597 (Photographs).

67. Cipla's medicament canister is moveable relative to the canister housing. When a patient uses Cipla's device, the patient presses down on Cipla's medicament canister. The canister moves downward relative to Cipla's canister housing. When the patient releases the device, the canister moves upward relative to the canister housing. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling); CIPLA-BDI_0156595, at -595, -597 (Photographs); CIPLA-BDI_0803837-38 (Design Drawings).

68. [redacted]

69. [redacted]

[redacted]

70. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla's Samples.

71. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 1.

d. "A Dose Counter Having an Actuation Member Having at Least a Portion Thereof Located in the Canister Housing for Operation by Movement of the Medicament Canister"

72. In my opinion, Cipla's ANDA Product comprises "a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister."

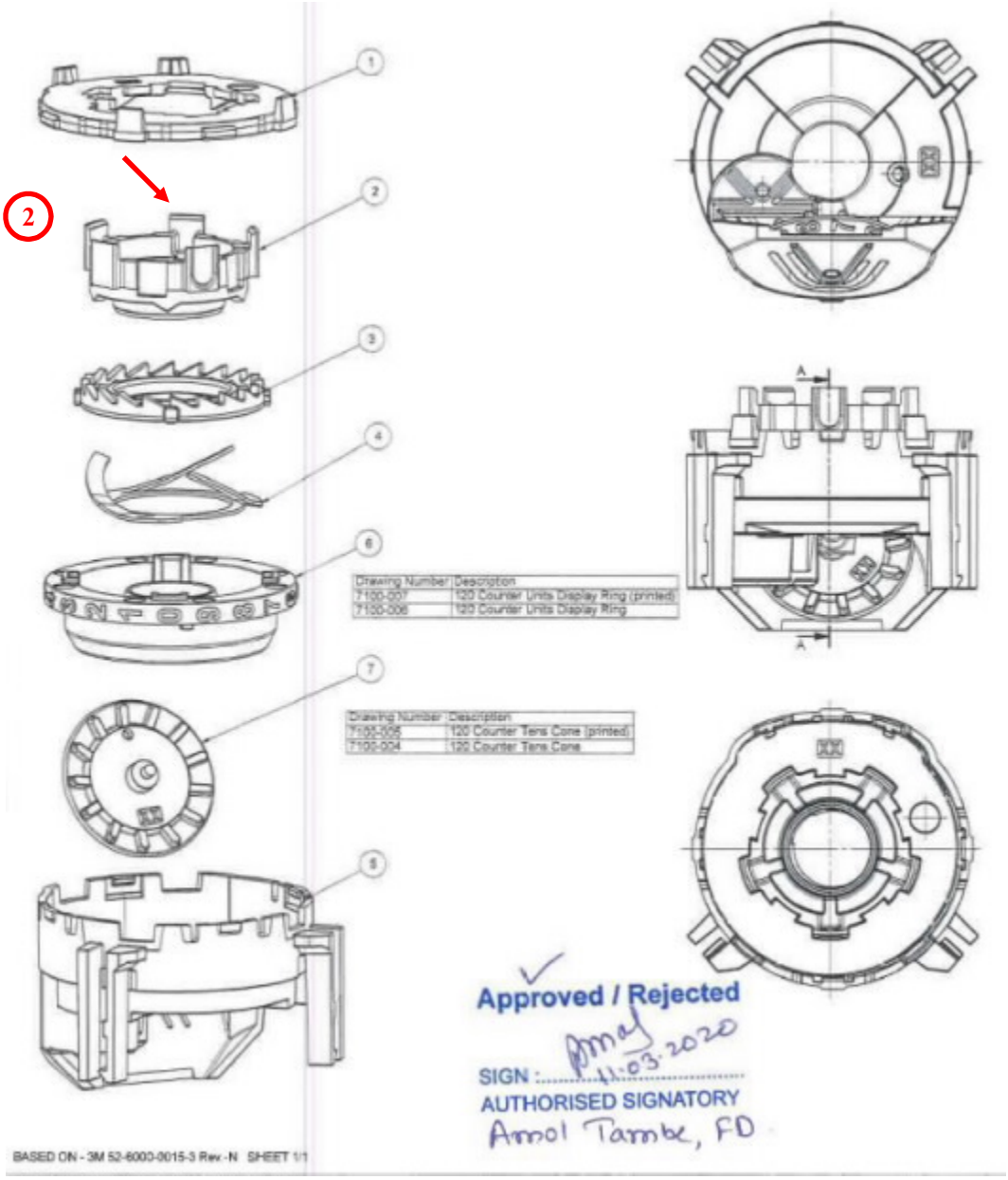
73. I have been informed that the parties have proposed different constructions for the term "actuation member." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "a component of the dose counter's actuator that transmits motion from the canister to the actuator." I have been informed that Defendants propose that the term should be construed to mean "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

74. **Teva's Proposed Construction.** In my opinion, Cipla's ANDA Product literally satisfies this limitation under Teva's proposed construction.

75. Cipla's ANDA Product comprises a dose counter, which has an "actuator" (2)

(i.e., what Cipla refers to as an "indexer"). *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawing); CIPLA-BDI_0803837-38 (Design Drawings).

76. As depicted below, Cipla's actuator (2) further has one or more "actuation members" (i.e., "castellations") (arrows) at its top, at least a portion of which extend into the canister housing.



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

77. When a patient presses down on Cipla's medicament canister, the medicament canister presses down on the castellations of the actuator, thereby transmitting motion from the medicament canister to the actuator. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling); CIPLA-BDI_0803837-38 (Design Drawings).

78. [redacted]

79. **Defendants' Proposed Construction.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed construction, both literally and under

the doctrine of equivalents.

80. Defendants' proposed construction requires the actuation member to be a "pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count." To the same effect, Cipla contends that Cipla's ANDA Product does not literally satisfy this limitation because Cipla's ANDA Product "does not have an 'actuation member,'" which it equates with "a pin extending through an aperture in a wall which separates the counter chamber and the canister housing." Cipla Non-Infringement Contentions, '289 Patent, Claim 1. In my opinion, Cipla's ANDA Product literally comprises such an element; and, even if it does not, it comprises an equivalent of this element.

81. As explained above in connection with Teva's proposed construction, Cipla's ANDA Product comprises an actuator (what Cipla refers to as an "indexer") which has one or more actuation members ("castellations") at its top. Each of those actuation members literally qualifies as a pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawing); CIPLA-BDI_0803837-38 (Design Drawings); Merriam-Webster's Collegiate Dictionary 940 (11th ed. 2007) ("something that resembles a pin esp. in slender elongated form <an electrical connector ~>").

82. The '289 Patent further confirms that Cipla's ANDA Product literally satisfies this limitation under Defendants' proposed construction. The '289 Patent describes that, in certain embodiments, the invention comprises an actuation member that transmits motion from the medicament canister to the actuator, which transmits that motion to other dose counter components. In certain examples, the actuation member may be a "pin." From those

descriptions, the POSA would understand that the "pin" was a slender, elongated structure that transmits motion from the medicament canister to the actuator. *See, e.g.*, '289 Patent, 5:26-34, 7:20-25, 12:13-16:37, Figs. 1, 6, 8, 10. The same is true of Cipla's actuation member. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawing); CIPLA-BDI_0803837-38 (Design Drawings).

83. Alternatively, to the extent that Cipla's ANDA Product does not literally satisfy this limitation under Defendants' proposed construction, Cipla's ANDA Product satisfies it under the doctrine of equivalents.

84. As explained above, the '289 Patent describes that, in the examples in which the actuation member is a "pin," the actuation member consists of a slender, elongated structure that transmits motion from the medicament canister to the actuator. *See, e.g.*, '289 Patent, 5:26-34, 7:20-25, 12:13-16:37, Figs. 1, 6, 8, 10.

85. To the extent that Cipla's actuation member(s) (i.e., the castellations on what Cipla refers to as an "indexer") do not literally qualify as "pins," they are insubstantially different from the '289 Patent's pins. Both consist of slender, elongated structure that transmit motion from the medicament canister to the actuator. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawing); CIPLA-BDI_0803837-38 (Design Drawings).

86. Additionally, both perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of transmitting motion from the medicament canister to the actuator, by way of providing a slender, elongated structure, to obtain the result of transmitting that motion to other dose counter components. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-

BDI_0156579 (Design Drawing); CIPLA-BDI_0803837-38 (Design Drawings).

87. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that (1) when a patient presses down on Cipla's medicament canister, Cipla's medicament canister presses down on the actuation member(s) (i.e., one or more of the castellations on what Cipla refers to as an "indexer"); (2) when Cipla's medicament canister presses down on the actuation member(s), the actuation member(s) cause the actuator (i.e., what Cipla refers to as the "indexer") to press down on other components of the dose counter, including, for example, what Cipla refers to as a "leaf spring" and a "units teeth ring," causing those components to move. *See, e.g.*, Cipla Samples.

e. "Wherein the Canister Housing Has an Inner Wall, and a First Inner Wall Canister Support Formation Extending Inwardly From a Main Surface of the Inner Wall"

88. In my opinion, Cipla's ANDA Product is an inhaler "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall."

89. I have been informed that the parties agreed that the term "inner wall" should be construed to mean "an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body"; the term "inner wall canister support formation" should be construed to mean "a formation arranged to reduce canister rocking"; and the term "main surface of the inner wall" should be construed to mean "inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament." I have applied those constructions in performing my analysis.

90. Cipla's canister housing has an inner wall, which faces towards the medicament

canister. Cipla's canister housing further has a series of nine inner wall canister support formations (seven of i.e., what Cipla refers to as "ribs" (solid arrows) and two of i.e., what Cipla refers to as "mounting tabs" (dashed arrow)), which extend inwardly from the main surface of the inner wall.

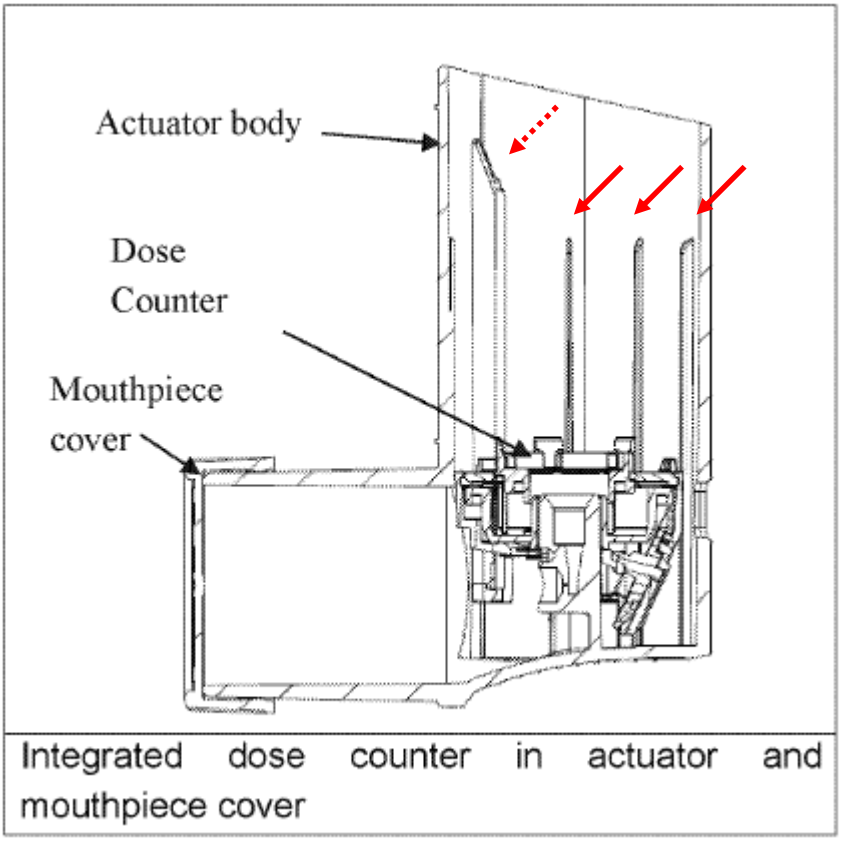


Figure 41: Actuator with Integrated Dose counter

See, e.g., CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); *see also* Cipla Samples; CIPLA-BDI_0803837-38 (Design Drawings).

91. Cipla's inner wall canister formations are arranged to prevent the medicament canister from rocking. As depicted above, Cipla's canister formations are arranged around the circumference of Cipla's inner wall and prevent Cipla's medicament canister from moving significantly in any lateral direction. When the medicament canister rocks towards the actuation member, the medicament canister comes into contact with the top of the inner wall canister

support formation, preventing it from rocking further. When the medicament canister rocks away from the actuation member, the medicament canister comes into contact with a lower portion of the inner wall canister support formation. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

92. [redacted]

93. [redacted]

[redacted]

94. The '289 Patent further confirms that Cipla's ANDA Product literally satisfies this limitation. The '289 Patent describes that, in certain embodiments, the inner wall canister support formations restrict the extent to which the medicament canister can move laterally, by extending into the canister housing, to reduce off-axis rotation (e.g., rocking). *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7. The same is true of Cipla's inner wall canister support formations. As explained above, Cipla's inner wall canister support formations reduce the extent to which the medicament canister can move laterally, by extending into the canister housing, to reduce rocking. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

95. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that Cipla's inner wall canister support formations (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs") (1) extend inwardly from the main surface of the inner wall of the medicament canister; and (2) are arranged to prevent the medicament canister from rocking. *See, e.g.*, Cipla Samples.

96. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 1.

f. "Wherein the Canister Housing Has a Longitudinal Axis X Which Passes Through the Center of the Central Outlet Port"

97. In my opinion, Cipla's canister housing "has a longitudinal axis X which passes

through the center of the central outlet port." As explained above, Cipla's ANDA Product has a central outlet port. *See, e.g.*, *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156595, at -595, -597 (Photographs); CIPLA-BDI_0803837-38 (Design Drawings); *supra* Section VIII.A.1.c ('289 Patent, Claim 1).

98. The '289 Patent explains that the longitudinal axis of the canister housing is the axis of the inhaler that passes longitudinally (i.e., vertically) through the central outlet port. '289 Patent, 6:50-58. I depict this below using Figures 7C and 7D.

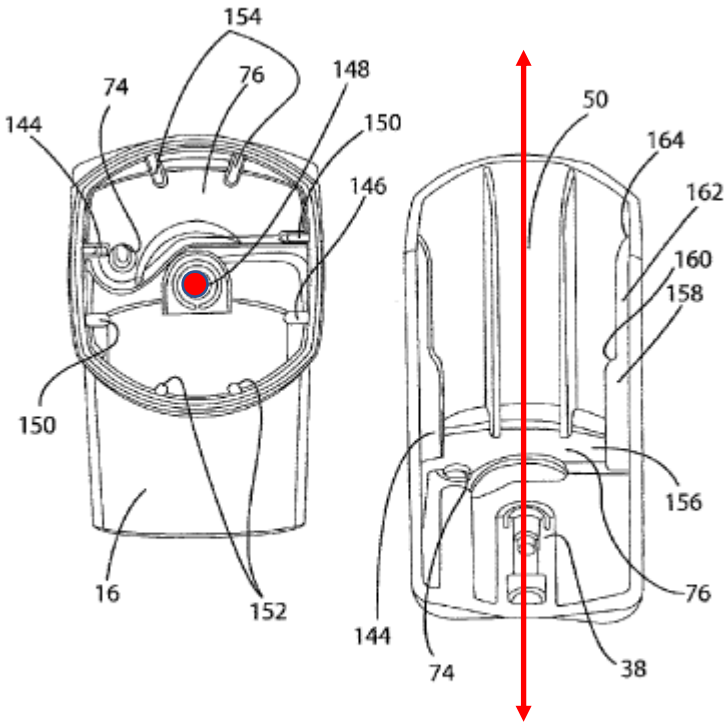
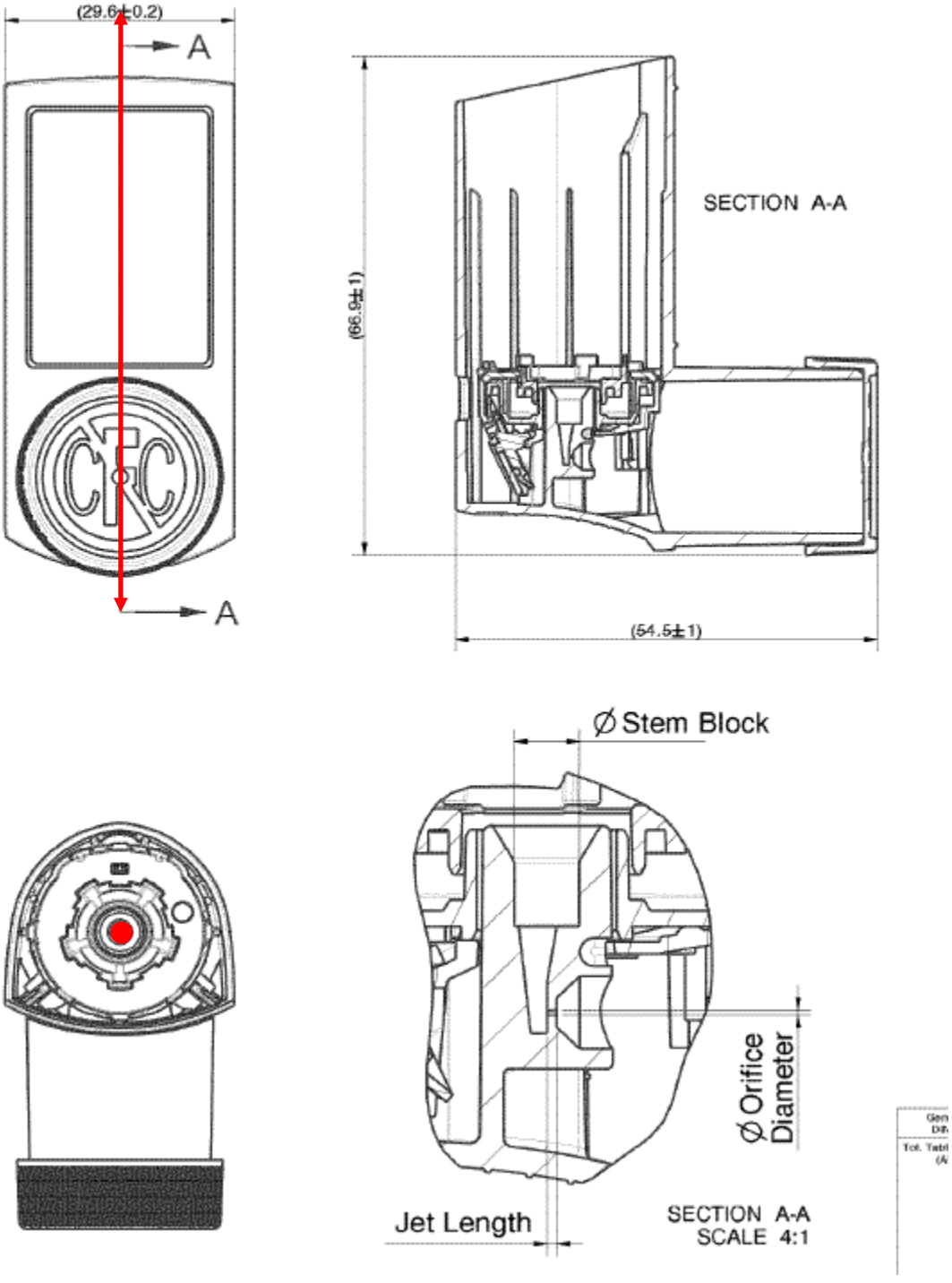


FIG. 7D FIG. 7C

See, e.g., '289 Patent, Figs. 7C, 7D. As the Figures depict, the longitudinal axis X appears as a line, when the inhaler is viewed from front-to-back (as in Figure 7C) and a point, when the inhaler is viewed from top-to-bottom (as in Figure 7D).

99. In the case of Cipla's ANDA Product, the longitudinal axis X is as follows.



See, e.g., CIPLA-BDI_0803837-38 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development).

100. [redacted]

101. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla Samples.

102. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 1.

g. "The Inner Wall Canister Support Formation, the Actuation Member, and the Central Outlet Port Lying in a Common Plane Coincident With the Longitudinal Axis X"

103. In my opinion, Cipla's ANDA Product satisfies the limitation that requires: "the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X."

104. I have been informed that the parties have proposed different constructions for the term "[lying or lie] in a common plane coincident with the longitudinal axis X." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to require that the claimed "[f]eatures lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the

valve stem block." I have been informed that Defendants propose that the term should be construed to require that those features are "aligned in a single plane such that a straight line can be drawn though the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

105. As explained above, Cipla's ANDA Product contains an "inner wall canister support formation" (the "ribs" and "mounting tabs"), "actuation member" (the castellations on the "indexer"), a "central outlet port," and "a longitudinal axis X which passes through the center of the central outlet port." Whether Cipla's ANDA Product satisfies this limitation therefore depends on whether it is possible to project from the longitudinal axis X one or more planes that pass through each of an inner wall canister support formation, actuation member, and central outlet port. In my opinion, it is possible to do so.

106. Below, I illustrate examples of planes (blue) that pass through the longitudinal axis X (red) using Figures 7C and 7D. As I illustrate below, the planes referenced in this limitation appear as planes passing through the central outlet port when the inhaler is viewed from front-to-back (as in Figure 7C) and lines when the inhaler is viewed from top-to-bottom (as in Figure 7D).

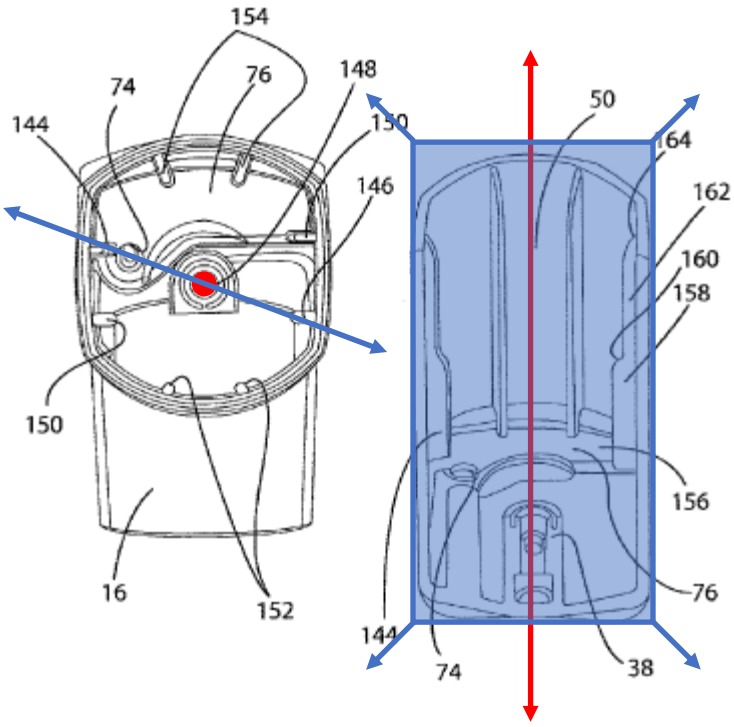


FIG. 7D FIG. 7C

See, e.g., '289 Patent, Figs. 7C, 7D. As noted, the planes illustrated above are exemplary only, and the limitation encompasses any plane that coincides with the central outlet port. When the inhaler is viewed from top-to-bottom (as in Figure 7D), such planes could be illustrated by rotating the line depicted above arbitrarily about the central outlet port.

107. The '289 Patent's prosecution history provides a similar illustration of this limitation. In a Response to an Office Action, dated March 7, 2016, the applicant illustrated this limitation using Figure 7D as follows:

By way of background to the instant invention recited in amended claim 1, the dash-dot line shown below depicts how the inner wall canister support formation 144, the actuation member at 74, and the central outlet port 148 lie in a common plane coincident with the longitudinal axis X at 148.

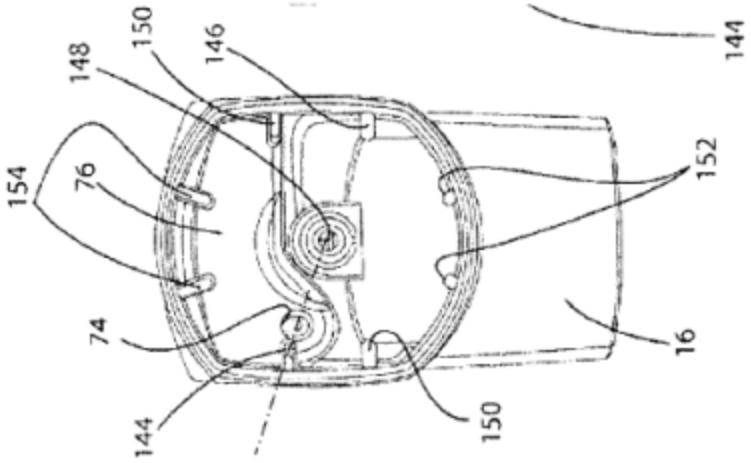


FIG. 7D

As explained in the instant application, this arrangement is "*highly advantageous in that the first inner wall canister support formation can prevent a canister from rocking too much relative to the main body of the inhaler. Since the canister may operate the actuation member of the dose counter, this substantially improves dose counting and avoids counter errors.*" Page 11, lines 16-20. Also, as set forth in the instant application, the claimed arrangement has the advantage of preventing the canister from rocking towards the position of the dose counter actuation member, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter (see page 11, lines 25-27, and page 27 lines 23-28). It is worth noting that the magnitude of the rocking does not have to be great for it to have a potentially detrimental effect on counter performance. By way of illustration, on page 31, lines 14-15 of the present application, it is disclosed that the distance between the average start and average reset position of such counters may be about 0.7 mm.

See, e.g., '289 Prosecution History, Office Action Response 5 (Mar. 7, 2016).

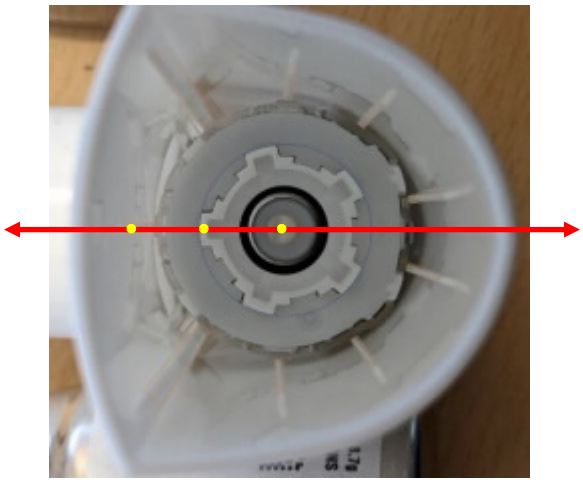
108. **Teva's Proposed Construction.** In my opinion, Cipla's ANDA Product literally satisfies this limitation under Teva's proposed construction.

109. To determine whether Cipla's ANDA Product satisfies this limitation, I inspected samples of Cipla's ANDA Product and the design drawings contained within Cipla's ANDA, which depict Cipla's dose counter when it is placed inside the inhaler. *See, e.g.*, Cipla Samples;

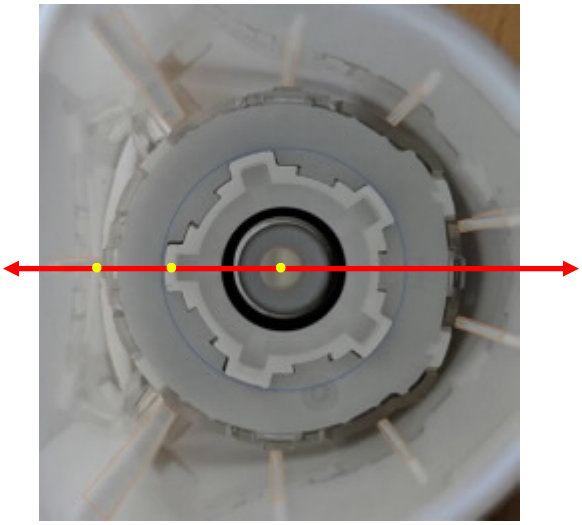
CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

110. The following figures are top-down photographs of samples of Cipla's ANDA Product, 40 mcg (Lot IB81152 (exp. 07/2020)) and 80 mcg (Lot IB90362 (exp. 09/2020)). The figures each identify a common plane that passes through the one of Cipla's inner wall canister support formations (which Cipla refers to as a "rib"), Cipla's actuation member (i.e., one of the castellations on what Cipla refers to as an "indexer), and the center of Cipla's central outlet port. The common planes depicted in these figures are merely illustrative; and it is possible to construct multiple common planes passing through the relevant components of Cipla's ANDA Product.

Cipla's ANDA Product, 40 mcg



Cipla's ANDA Product, 80 mcg



111. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise an "actuation member" and, alternatively, because "it is not possible to draw a single plane through any structure which could be considered the 'actuation member,' the central outlet port, and the canister support structures." Cipla Infringement Contentions, '289 Patent, Claim 1. To support that assertion, Cipla relies on the applicant's statements regarding U.S. Patent Publication No. 2006/0107949 ("Davies") during the prosecution of the '289 Patent. *See* Office Action Response (Mar. 7, 2016).[4] I have reviewed the prosecution history and reference, and I disagree. As explained above, Cipla's ANDA Product comprises an actuation member, central outlet port, and inner wall canister support formation, all of which lie on a common plane coincident with the longitudinal axis X. Nothing in the examiner's or applicant's statements clearly and unmistakably shows that the arrangement of Cipla's inner wall canister support formation, actuation member, and central outlet port do not satisfy the requirements of this limitation or that the applicant's statements

[4] Cipla's Non-Infringement Contentions incorrectly identify March 3, 2007, as the date of the response.

bear anything more than a tangential relationship to that analysis. *See* Office Action Response (Mar. 7, 2016); Davies. I address Cipla's contention that Cipla's ANDA Product does not comprise an "actuation member" above. *See, e.g.*, *supra* Section VIII.A.1.d ('289 Patent, Claim 1).

112. **Defendants' Proposed Construction.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed construction, at a minimum, under the doctrine of equivalents.

113. Defendants' proposed construction requires the "canister support formation located directly adjacent to the actuation member." To the extent that Cipla's ANDA Product does not literally satisfy this requirement, it satisfies it under the doctrine of equivalents.

114. The '289 Patent describes that, in certain embodiments: "The canister housing may have a longitudinal axis which passes through a central outlet port thereof, the central outlet port being arranged to mate with an outer canister fire stem of a medicament canister, the inner wall canister support formation, the actuation member and the outlet port lying in a common plane coincident with the longitudinal axis. Accordingly, this construction may prevent the canister from rocking towards the position of the dose counter actuation member, thereby minimising errors in counting." *See, e.g.*, '289 Patent, 6:34-58. Thus, the POSA would understand that the claimed arrangement restricts the extent to which the medicament canister can move towards the actuation member, by placing an inner wall canister support formation on a common plane with the actuation member, to reduce rocking in the direction of the actuation member. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7.

115. Because the '289 Patent describes the claimed arrangement with respect to reducing rocking in the direction of the actuation member, the POSA would understand that it

was not an essential aspect of the inventions whether the actuation member were located directly adjacent to the inner wall canister support formation instead of another position that would prevent rocking in that direction (for example, on a common plane coincident with the inner wall canister support formation). *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7. Thus, to the extent that, in certain embodiments, the actuation member is located directly adjacent to the inner wall canister support formation, the POSA would understand this to be an inessential aspect of the inventions as a whole. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7.

116. In my opinion, any differences between the claimed arrangement and Cipla's ANDA Product are insubstantial. Both comprise an arrangement of structures (in the case of Cipla's ANDA Product, what Cipla refers to as "ribs" or "mounting tabs"), that restrict the extent to which the medicament canister can rock towards the actuation member (in the case of Cipla's ANDA Product, the castellations on what Cipla refers to as an "indexer") by placing one or more of those structures on a plane that passes through the actuation member and the central outlet port. To the extent that Cipla's ANDA Product does not comprise an inner wall canister support formation, the POSA would understand this to be inessential. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

117. Alternatively, Cipla's ANDA Product and the claimed arrangement function perform substantially the same function in substantially the same way to obtain the same result. Both perform substantially the function of restricting the extent to which the medicament canister can move towards the actuation member, by way of restricting the amount of space that the canister can move in that direction, to obtain the result of reducing rocking in that direction. This is true even if Cipla's inner wall canister support formation is not directly adjacent to the

actuation member. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

118. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that Cipla's ANDA Product comprises (a) inner wall canister support formations (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs"), (b) an actuation member, and a central outlet port; (2) Cipla's inner wall canister support formations extend inwardly from the main surface of the inner wall of the medicament canister; (3) with respect to Cipla's ANDA Product, it is possible to construct multiple common planes through each of an inner wall canister support formation, an actuation member, and the central outlet port; and (4) the arrangement of Cipla's inner wall canister support formation, actuation member, and central outlet port prevents the medicament canister from rocking in the direction of the actuation member. *See, e.g.*, Cipla Samples.

2. '289 Patent, Claim 2

119. Claim 2 of the '289 Patent recites: "The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

120. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 1, as explained above. In my opinion, Cipla's ANDA Product further satisfies the limitation requiring "wherein the medicament canister is movable relative to the dose counter."

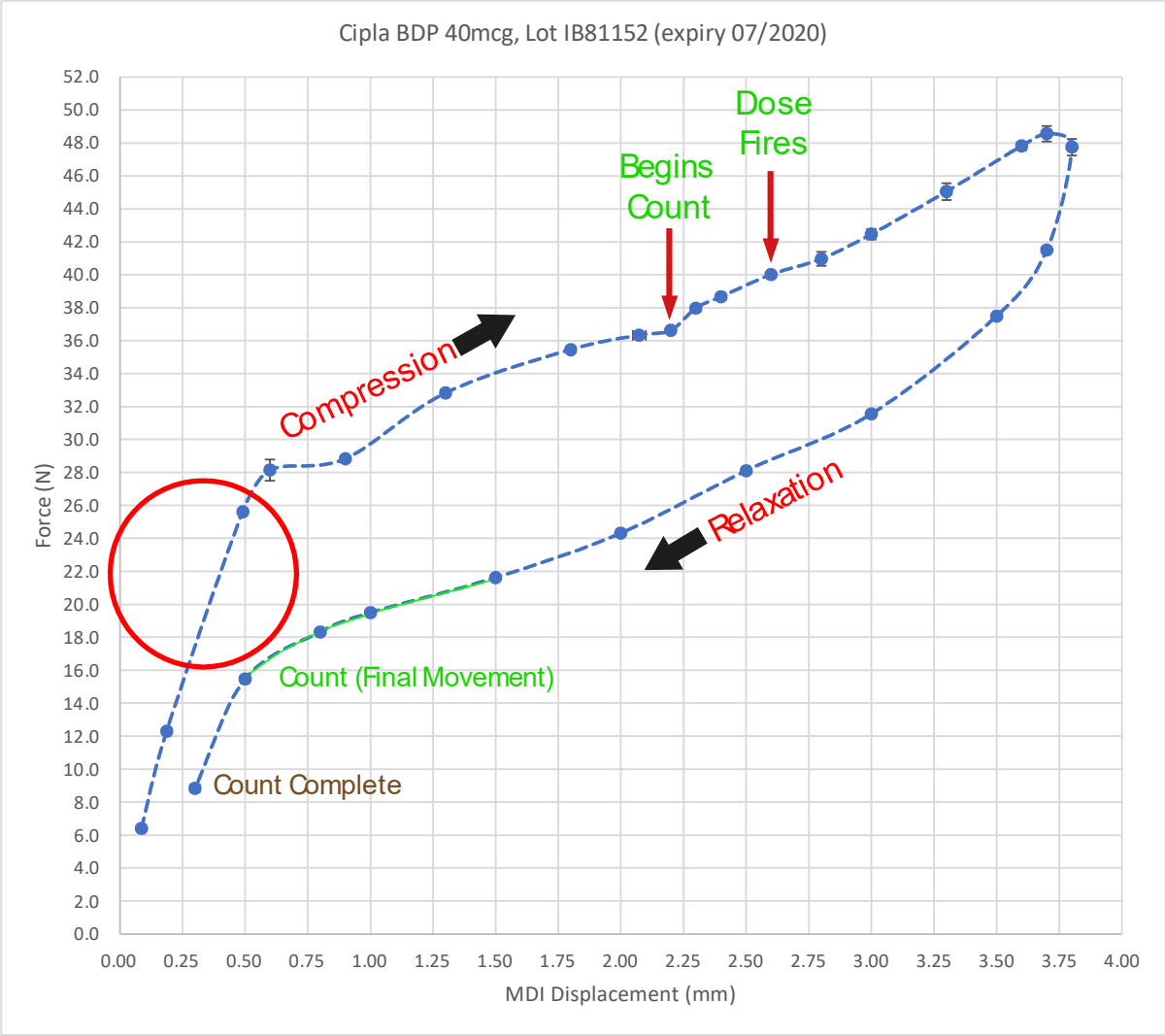
121. When Cipla's ANDA Product is assembled, there is a gap between Cipla's medicament canister and its dose counter. Thus, when the patient presses down on the medicament canister, it moves through the gap before coming into contact with the dose counter (and, by extension, any of the dose counter's components), thus, moving relative to the dose

counter. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

122. Exhibit C describes experiments measuring the amount of force and distance needed to cause Cipla's ANDA Product to fire and count. Below, I reproduce two force-displacement curves resulting from that experiment.

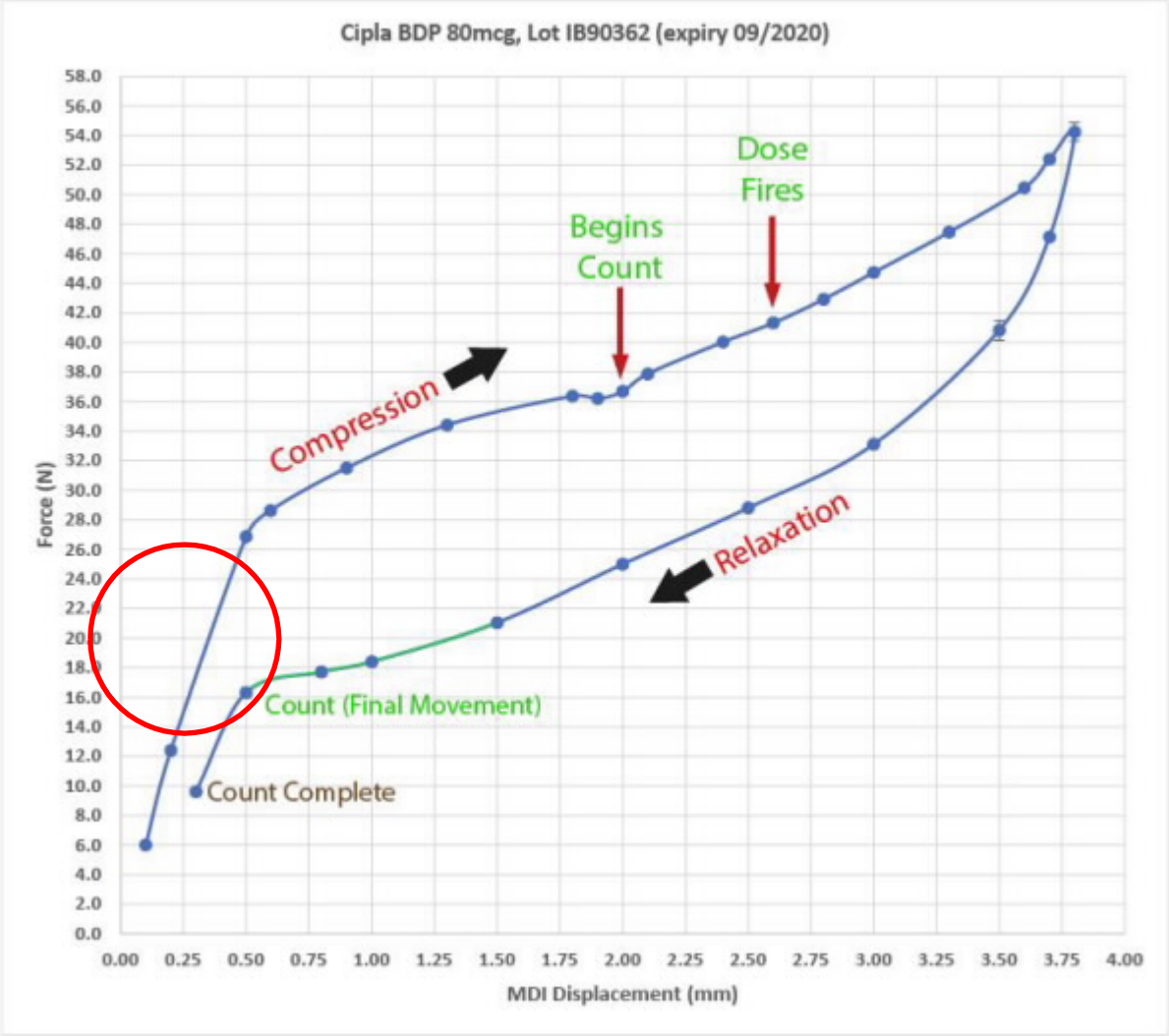
Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Replicates, n = 5



Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Replicates, n = 5



As the circled portions of the above force-displacement diagrams curves illustrate, Cipla's medicament canister moves through a gap before it comes into contact with Cipla's dose counter, after which the resistance increases significantly.

123. [redacted]

[redacted]

124. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) there is an initial gap between Cipla's medicament canister and dose counter; (2) when a patient presses down on Cipla's medicament canister, it moves downward relative to the dose counter; and (3) after Cipla's medicament canister makes contact with the dose counter, the medicament canister remains moveable relative to at least some dose counter components, including (what Cipla refers to as) the units teeth ring, units display ring, and tens cone. *See, e.g.*, Cipla Samples.

125. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 2. I disagree for the reasons stated above in connection with that claim. *See, e.g.*, *supra* Section VIII.A.1 ('289 Patent, Claim 1).

3. '289 Patent, Claim 3

126. Claim 3 of the '289 patent recites: "The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

127. I have been informed that the parties have agreed that the term "inner wall through which a portion of the actuation member extends" should be construed to mean "an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament." I have applied this construction in my analysis.

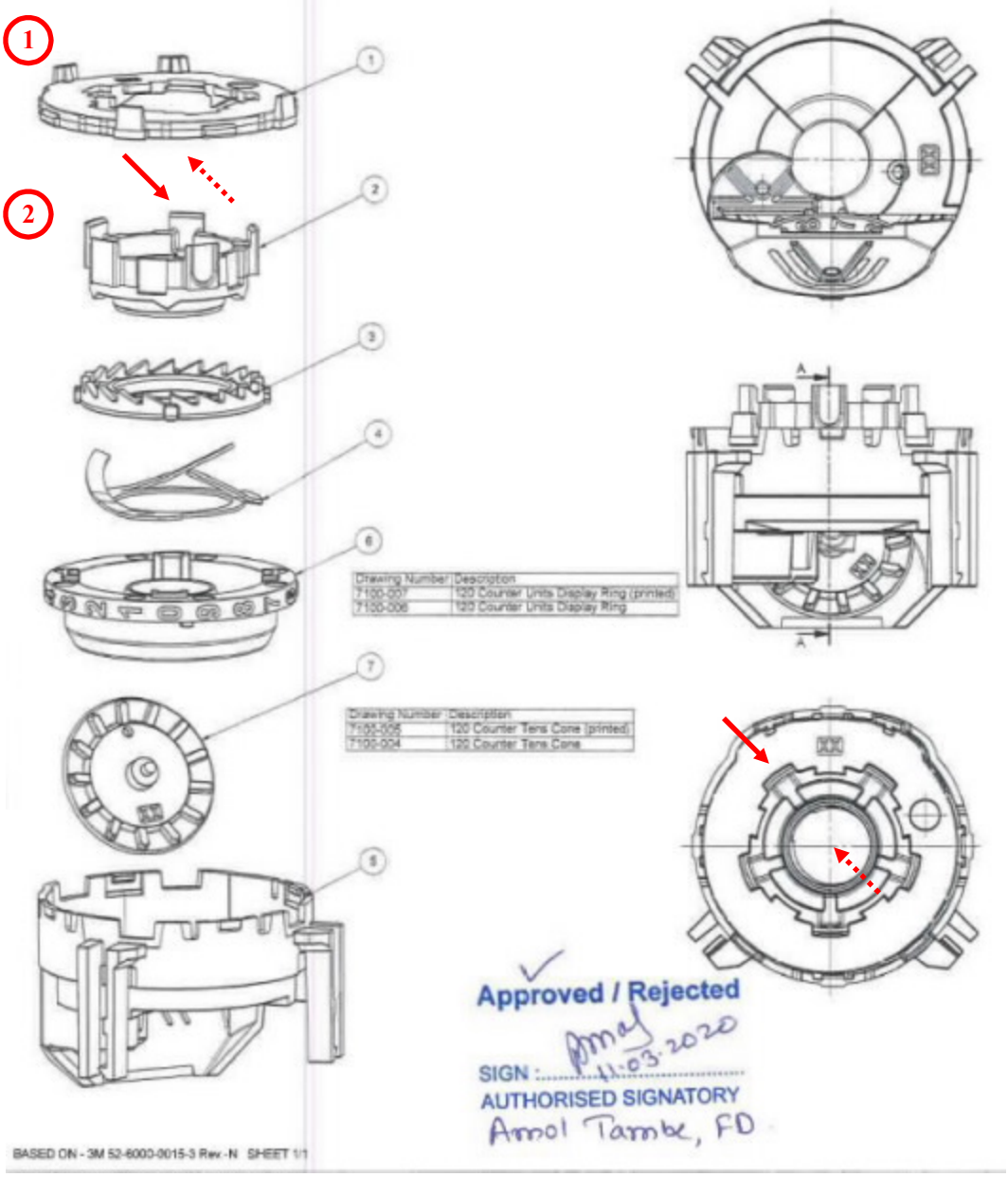
128. I have been informed that the parties have proposed different constructions for the

term "aperture." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "an opening or open space: hole." I have been informed that Defendants propose that the term should be construed to mean "hole." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

129. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 1, as explained above. In my opinion, Cipla's ANDA Product further satisfies the limitation requiring "an aperture formed in the inner wall through which the portion of the actuation member extends." As explained above, Cipla's dose counter comprises one or more actuation members ("castellations"). *See, e.g.*, *supra* Section VIII.A.1.d. When Cipla's ANDA Product is assembled, those actuation members extend through an opening, open space, or hole in a component (which Cipla refers to as a "lid"), which, together with the inner wall of the canister housing, covers the components of Cipla's dose counter and separates them from portion of the canister housing that contains the medicament canister. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

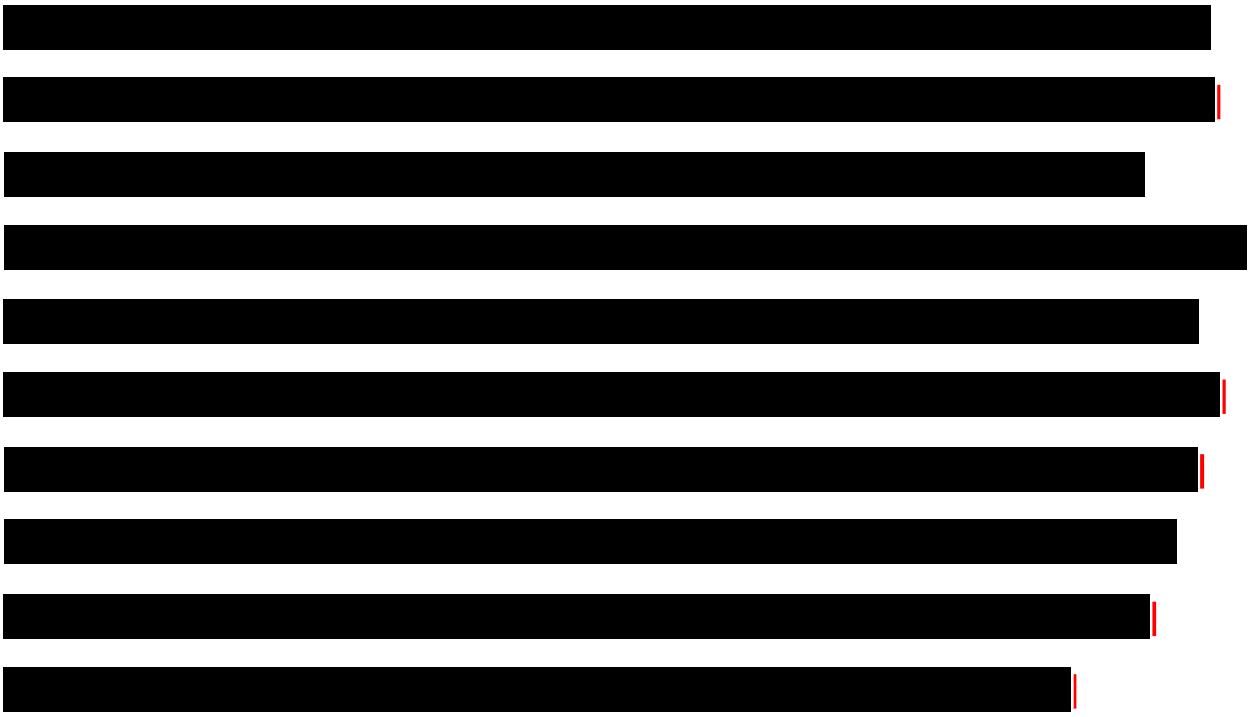
130. For purposes of my analysis, the portion of Cipla's lid through which Cipla's one or more actuation members extend can be accurately characterized as an "opening," "open space," or "hole." Which term is used does not affect my conclusions.

131. Below, I illustrate the castellations (solid arrows) on (what Cipla refers to as) the "indexer" (2) and the aperture (dashed arrows) in (what Cipla refers to as) the "lid" (1).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

132. [redacted]



133. Cipla contends that Cipla's ANDA Product does not comprise an "actuation member," and, alternatively, does not comprise an "inner wall through which the portion of the actuation member extends," which it equates with "a wall which separates the counter chamber and the canister housing," which it equates with "a wall which separates the counter chamber and the canister housing." Cipla Non-Infringement Contentions, '289 Patent, Claim 3. I disagree. As I explain above, Cipla's ANDA Product literally comprises an aperture (i.e., a hole in what Cipla refers to as a "lid") through which the actuation member (i.e., one or more of the castellations on what Cipla refers to as an "indexer"). Together with the inner wall of the canister housing, Cipla's aperture covers the components of Cipla's dose counter and separates them from portion of the canister housing that contains the medicament canister. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings). I address Cipla's contention that Cipla's ANDA Product does not comprise an "actuation member" in connection with claim 1 of the '289 Patent.

See, e.g., *supra* Section VIII.A.1.d ('289 Patent, Claim 1).

134. Additionally, in my opinion, to the extent that Cipla's ANDA Product does not satisfy this limitation literally, it does so under the doctrine of equivalents.

135. The '289 Patent describes that, in certain embodiments, the invention comprises an actuator that extends through the a "communication aperture to transmit motion to the actuator." *See, e.g.*, '289 Patent, 6:20-34 Fig. 7B, 7C. As that description suggests, the aperture permits the actuation member to transmit motion from the medicament canister to the actuator by creating an opening, open space, or hole in the inner wall through which the actuation member can extend. This permits the medicament canister to press down against the actuation member, while separating the other dose counter components from the portion of the canister housing that contains the medicament canister. *See, e.g.*, '289 Patent, 6:20-34 Fig. 7B, 7C.

136. To the extent that Cipla's ANDA Product does not literally satisfy this limitation, the differences between the opening, open space, or hole in Cipla's lid are insubstantially different from the claimed "aperture." Both consist of openings that permit the actuation member to transmit motion from the medicament canister to the actuator, by creating an opening, open space, or hole through which the actuation member can extend, which permits the medicament canister to press down against the actuation member, while separating the other dose counter components from the portion of the canister housing that contains the medicament canister. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

137. Alternatively, the opening, open space, or hole in Cipla's lid and the claimed "aperture" perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of allowing the actuation member to transmit motion

from the medicament canister to the actuator, by way of creating an opening, open space, or hole in the inner wall through which the actuation member can extend, to obtain the result of allowing the dose counter to actuate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

138. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises an actuation member (i.e., one or more of the castellations on what Cipla refers to as an "indexer") and an aperture (i.e., an opening, open space, or hole in what Cipla refers to as a "lid"); (2) Cipla's actuation member extends through the aperture; and (3) together with the inner wall of the canister housing, Cipla's aperture covers the components of Cipla's dose counter and separates them from portion of the canister housing that contains the medicament canister. *See, e.g.*, Cipla's Samples.

139. Cipla also contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 3. I disagree for the reasons stated above in connection with those claims. *See, e.g.*, *supra* Section VIII.A.1 ('289 Patent, Claim 1).

4. '289 Patent, Claim 4

140. Claim 4 of the '289 patent recites: "The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

141. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 1, as explained above. As explained above, Cipla's canister housing has a series of inner wall canister

support formations (which Cipla's variously refers to as "ribs" or "mounting tabs"), which extend inwardly from the main surface of the inner wall.

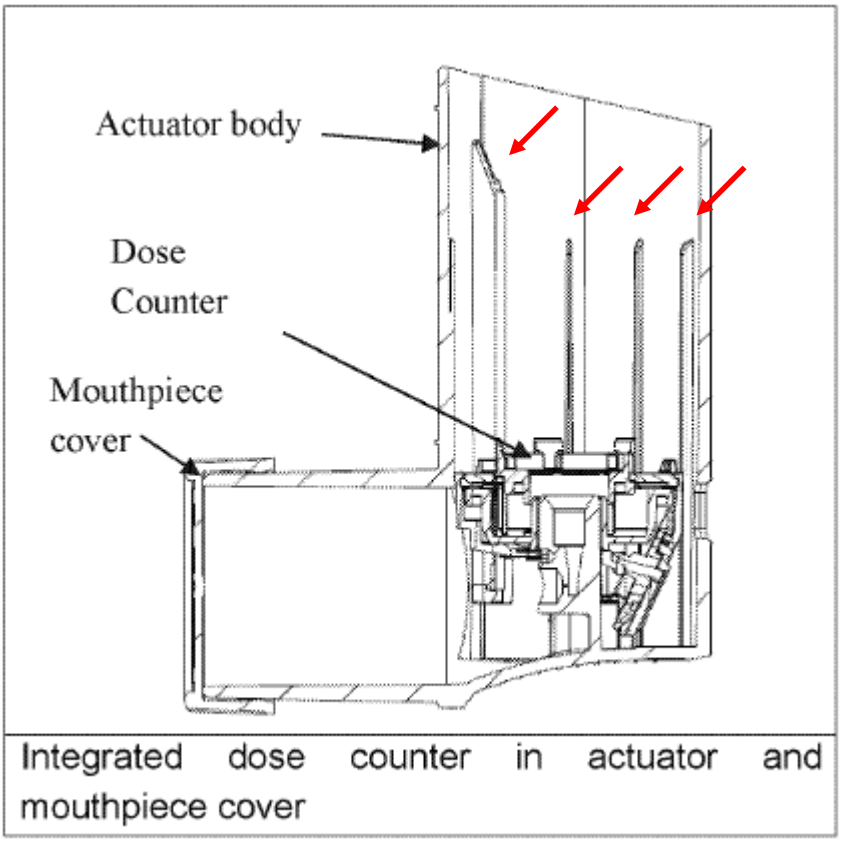


Figure 41: Actuator with Integrated Dose counter

See, e.g., CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); *see also* Cipla Samples; CIPLA-BDI_0803837-38 (Design Drawings). In my opinion, Cipla's canister housing further has a first inner wall canister support formation that comprises a support rail which extends longitudinally along an inside surface of the main body. As depicted above, each of the inner wall canister support formations comprises a support rail which extends longitudinally along an inside surface of the main body. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

142. [redacted]

[redacted]

143. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 4. I disagree for the reasons stated above in connection with that claim. *See, e.g.*, *supra* Section VIII.A.1 ('289 Patent, Claim 1).

5. '289 Patent, Claim 5

144. Claim 5 of the '289 Patent recites: "The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

145. I have been informed that the parties have proposed different constructions for the term "step[(s)] formed thereon." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning in view of the claims, specification, and prosecution history, to mean "a location of changing width dimension thereon." I have been informed that Defendants have proposed that the term should be construed to mean: "A stepwise increase in the extent to which the support rail extends inwardly." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

146. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 4, as explained above. As explained above, Cipla's canister housing has a series of inner wall canister

support formations (which Cipla variously refers to as "ribs" or "mounting tabs"), which comprise support rails which extends longitudinally along an inside surface of the main body.

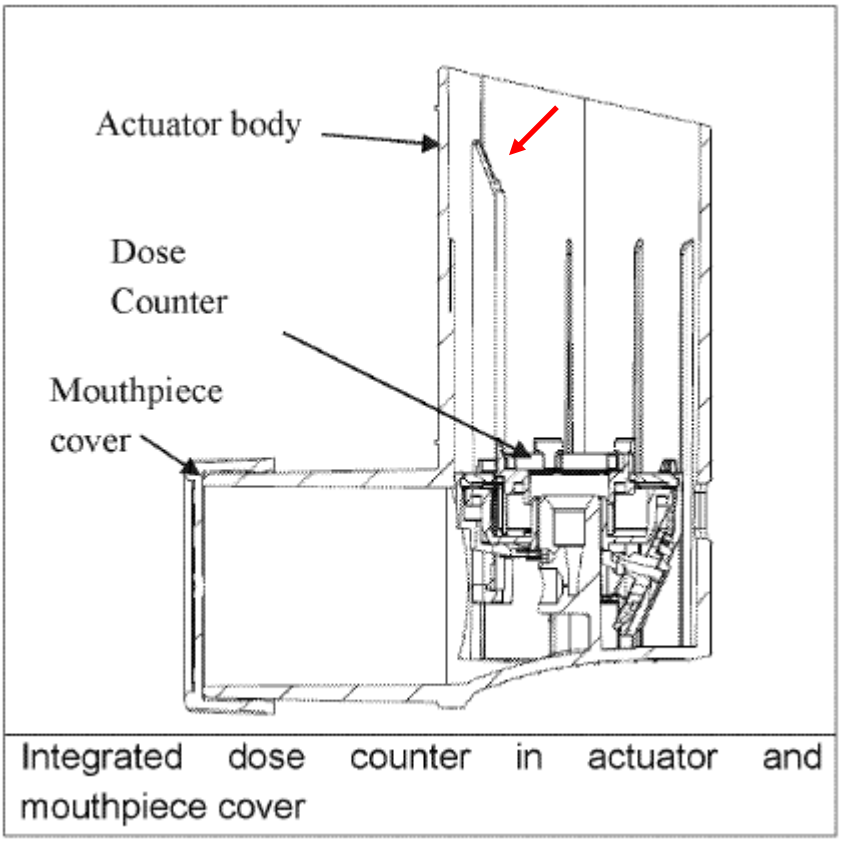


Figure 41: Actuator with Integrated Dose counter

See, e.g., CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); *see also* Cipla Samples; CIPLA-BDI_0803837-38 (Design Drawings). In my opinion, Cipla's ANDA Product further comprises a support rail that includes a step formed thereon. As depicted above, Cipla's mounting tabs and ribs vary in width (i.e., the extent to which they extend horizontally into the canister housing) at certain points along their length. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings). In my opinion, this variation in the width can be accurately characterized as either "a location of changing width dimension" or a "stepwise increase in the extent to which the support rail extends inwardly." Which proposed construction is used does not affect my conclusions.

147. [redacted]

148. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises support rails (i.e., what Cipla refers to as "ribs" or "mounting tabs"); (2) Cipla's support rails have step-wise increases in the extent to which they extend inwardly into the canister housing; and (3) the shape of Cipla's support rails facilitates step-wise insertion of the medicament canister into the canister housing. *See, e.g.*, Cipla Samples.

149. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1 and 4 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 5. I disagree for the reasons stated above in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.A.4 ('289 Patent, Claims 1, 4).

6. '289 Patent, Claim 6

150. Claim 6 of the '289 Patent recites "The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

151. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 4, as explained above. As explained, Cipla's canister housing has a series of inner wall canister

support formations (which Cipla variously refers to as "ribs" or "mounting tabs"), which comprise support rails which extends longitudinally along an inside surface of the main body.

152. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. *See, e.g.*, Cipla Samples.

153. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1 and 4 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 6. I disagree for the reasons stated above in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.A.4 ('289 Patent, Claims 1, 4).

7. '289 Patent, Claim 7

154. Claim 7 of the '289 Patent reads as follows: "The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

155. I have been informed that the parties have proposed different constructions for the term "positioned at opposite ends of the inside surface of the main body to face each other." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning in view of the claims, specification, and prosecution history, to mean "located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other." I have been informed that Defendants have proposed that the term should be construed to mean "positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

156. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 6, as explained above. As explained in connection with claims 1 and 6, Cipla's ANDA Product comprises a plurality of support rails which extend longitudinally along an inside surface of the main body.

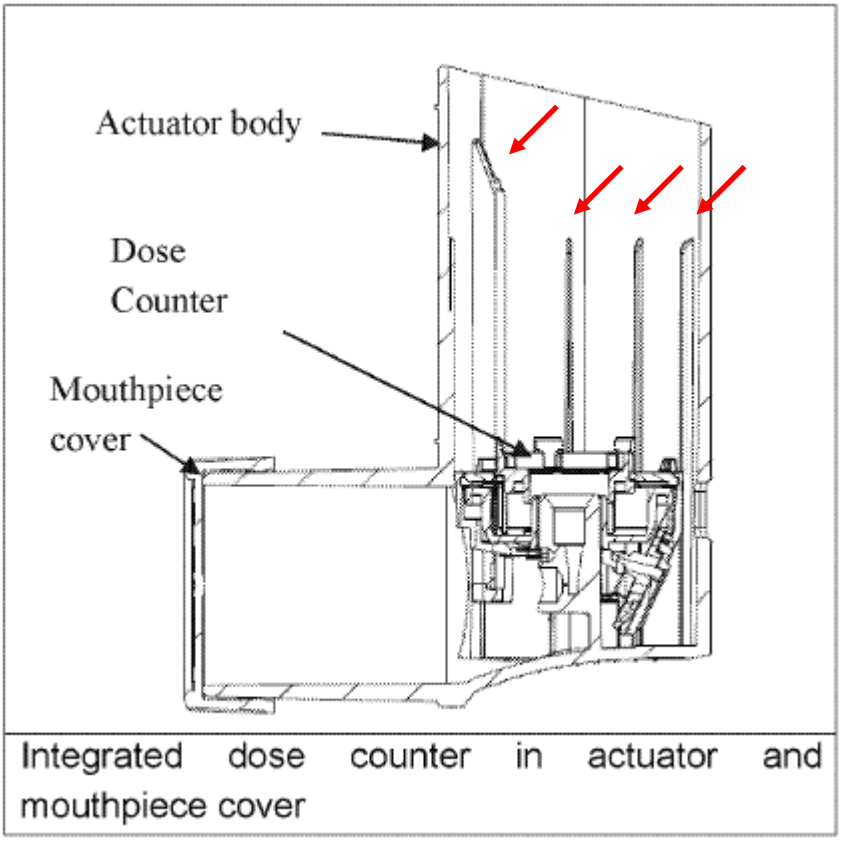


Figure 41: Actuator with Integrated Dose counter

See, e.g., CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); *see also* Cipla Samples; CIPLA-BDI_0803837-38 (Design Drawings).

157. As shown in the photographs of samples of Cipla's ANDA Product, 40 mcg (Lot IB81152 (exp. 07/2020)) and 80 mcg (Lot IB90362 (exp. 09/2020)) included in my analysis of claim 1 and reproduced below, several of those support rails are positioned at opposite ends of the inside surface of the main body to face each other.

Cipla's ANDA Product, 40 mcg

Cipla's ANDA Product, 80 mcg

See also Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings); *supra* Section VIII.A.1.g ('289 Patent, Claim 1).

158. In my opinion, these support rails can be accurately characterized as "positioned at opposite ends of the inside surface of the main body to face each other" or "located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other." Which proposed construction is used does not affect my conclusions.

159. Cipla contends that Cipla's ANDA Product "does not have support rails positioned at opposite ends of the inside surface of the main body to face each other. CIPLA-BDI_0156595; CIPLA-BDI_0156597; CIPLA_P_000001-50; CIPLA-BDI_0156579; and CIPLA-BDI_0004411-705." Cipla Non-Infringement Contentions, '289 Patent, Claim 7. I have reviewed the materials Cipla cites, and I disagree. As I explain above, Cipla's samples and documents establish that Cipla's ANDA Product does, in fact, satisfy this limitation. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

160. Additionally, in my opinion, to the extent that Cipla's ANDA Product does not satisfy this limitation literally, it does so under the doctrine of equivalents.

161. The '289 Patent states that in certain embodiments, two support rails may be "diametrically opposed" to each other. In these embodiments, the positioning of the support rails provides a "maximum clearance" between the medicament canister (20) and the support rails, which is determined based on the position of actuator and the support rails. The "clearance in this plane means that the canister 20 can only rock backwards and forwards in this plane towards away from the actuation pin 34. A relatively small distance and this therefore prevents the canister wobbling and changing the height of the actuation pin 34 a as to undesirably alter the accuracy of the dose counter 36. This is therefore highly advantageous." '289 Patent, 15:33-16:3; Figs. 7A-7D. Thus, the POSA would understand that the positioning of the support rails restricts the extent to which the medicament canister can move laterally in the canister housing along a specific plane, by reducing the amount of space that the canister can move on that plane, which reduces off-axis rotation (e.g., rocking) on that plane.

162. Assuming for argument's sake that this claim requires the support rails to be

something like "diametrically opposed" and Cipla's support rails do not satisfy that requirement, in my opinion, the positioning of Cipla's support rails is insubstantially different from the claimed positioning. In both cases, the canister housing comprises support rails that are arranged opposite each other such that it is possible to construct a plane that passes through each of them and the central outlet port. In each case, this results in restricting Cipla's medicament canister from moving on that particular plane. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

163. Alternatively, in my opinion, the positioning of Cipla's support rails and the claimed positioning performs substantially the same function in substantially the same way to obtain the same result. Both perform the function of restricting the extent to which the medicament canister can move towards the actuation member in the canister housing along a specific plane, by way of reducing the amount of space that the canister can move on that plane, to obtain result of reducing rocking on that plane. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

164. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises a plurality of support rails (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs"); (2) at least two of Cipla's support rails are on opposite ends of the inside surface of the main wall; and (3) the positioning of Cipla's support rails prevents Cipla's medicament canister from moving on the plane that passes through the support rails and the central outlet port. *See, e.g.*, Cipla Samples.

165. Cipla also contends that it does not infringe this claim for the same reasons that it

contends that it does not infringe claims 1, 4, and 6 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 7. I disagree for the reasons stated above in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.A.4, VIII.A.6 ('289 Patent, Claims 1, 4, 6).

8. '289 Patent, Claim 8

166. Claim 8 of the '289 Patent reads as follows: "The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

167. Cipla's ANDA Product satisfies the limitations of claim 4, as explained above. As explained above, Cipla's ANDA Product has a series of inner wall canister support formations (which Cipla variously refers to as "ribs" or "mounting tabs"), which comprise support rails which extends longitudinally along an inside surface of the main body.

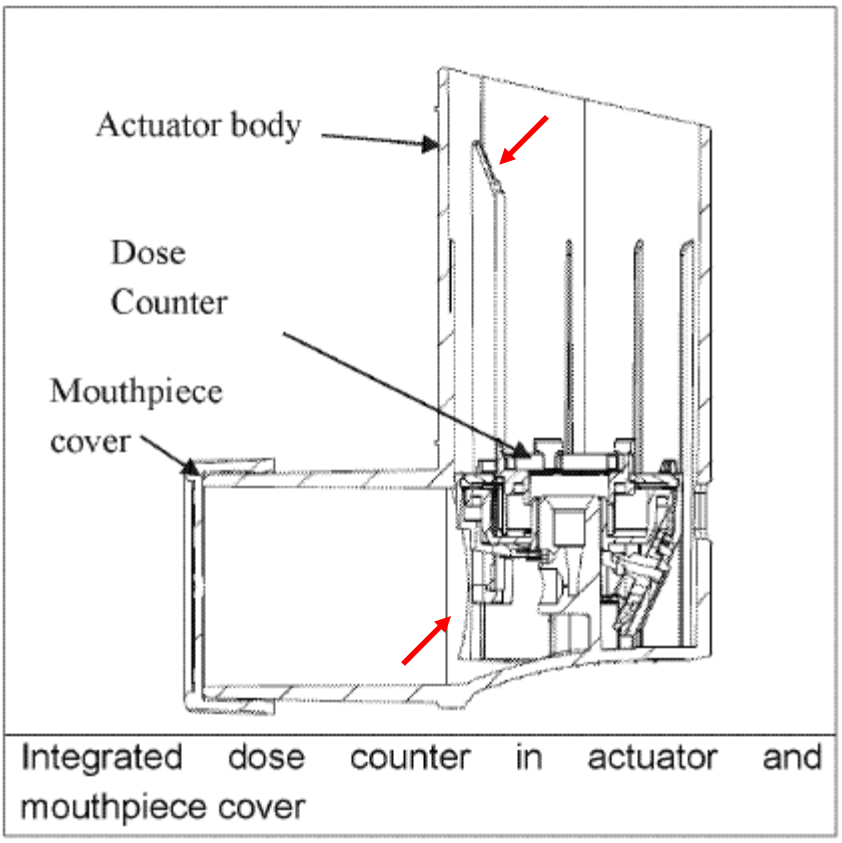


Figure 41: Actuator with Integrated Dose counter

See, e.g., CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); *see also* Cipla Samples; CIPLA-BDI_0803837-38 (Design Drawings). In my opinion, Cipla's support rails further include two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body. As depicted above, Cipla's ANDA Product comprises at least one support rail that includes two steps, which are spaced apart longitudinally alongside the inside surface of the main body. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

168. [redacted]

[redacted]

169. Cipla contends that it does not infringe this claim because, purportedly, Cipla's ANDA Product "does not literally include a "support rail" with "two steps formed thereon." Cipla Non-Infringement Contentions, '289 Patent, Claim 8. I disagree. As I explain above, Cipla's ANDA Product includes at least one support rail that literally satisfies this limitation. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

170. Additionally, to the extent that Cipla's ANDA Product does not satisfy this limitation literally, it does so under the doctrine of equivalents. The '289 Patent describes that, in certain embodiments, the inner wall canister support formations may be stepped. In these embodiments, the shape of the inner wall canister support formations in these embodiments facilitates easy insertion of the medicament canister into the canister housing, by altering the shape of the inner wall support formations at certain points along their length, to facilitate step-wise insertion of the medicament canister into the canister housing. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7.

171. The shapes of Cipla's support rails are to the same effect. Cipla's support rails (i.e., what Cipla refers to as "ribs" or "mounting tabs") have broader and narrower sections, which facilitate easy, step-wise insertion of the medicament canister into the canister housing. During the first stage of insertion, the narrower sections of the support rails provide for greater tolerances with respect to the angle at which the canister is inserted. When the medicament canister reaches the first step, the shape of the support rails guides the medicament canister

towards the center of the canister housing, facilitating insertion in subsequent stages. Several of the support rails further comprise a second step at the bottom to avoid interfering with the orifice through which the medicament fires. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

172. To the extent that the shapes of Cipla's support rails (i.e., what Cipla refers to as "ribs" or "mounting tabs") do not literally qualify as "steps," they are insubstantially different. Both comprises structures that facilitate easy insertion of the medicament canister into the canister housing, by providing broader and narrower sections, to facilitate step-wise insertion of the medicament canister into the canister housing without interfering with other components. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

173. Alternatively, the shapes of Cipla's support rails (i.e., what Cipla refers to as "ribs" or "mounting tabs") and the claimed "steps," perform substantially the same function in substantially the same way to obtain the same result. Both perform the same of facilitating easy insertion of the medicament canister into the canister housing, by way of providing broader and narrower sections, to obtain the result of facilitating step-wise insertion of the medicament canister into the canister housing without interfering with other components. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

174. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises support rails (i.e., what Cipla refers to as "ribs" or "mounting tabs"); (2) Cipla's support rails have a first step-wise increases in the extent to which they extend

inwardly into the canister housing at their top; (3) at least some of Cipla's support rails have a second step-wise change in the extent to which they extend inwardly into the canister housing at their bottom; and (4) the shape of Cipla's support rails facilitates step-wise insertion of the medicament canister into the canister housing without interfering with other components, such as the orifice through which the medicament fires. *See, e.g.*, Cipla Samples.

175. Cipla also contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1 and 4 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '289 Patent, Claim 8. I disagree for the reasons stated above in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.A.4 ('289 Patent, Claims 1, 4).

B. U.S. Patent No. 9,808,587 ('587 Patent)

1. '587 Patent, Claims 1-8

176. Claim 1 of the '587 Patent and claim 1 of the '289 Patent are identical, except for the following **underlined** language:

'289 Patent, Claim 1	**'587 Patent, Claim 1**
1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through	1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through

the center of the central outlet port, **the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.**	the center of the central outlet port, **wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.**

Whereas claim 1 of the '289 Patent requires the inner wall canister support formation, the actuation member, and the central outlet port to lie in a common plane coincident with the longitudinal axis X, claim 1 of the '587 Patent additionally requires those components to lie in a common plane coincident with the longitudinal axis X, "such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler."

177. Claims 2-8 of the '587 Patent depend directly or indirectly from claim 1 and are identical to claims 2-8 of the '289 Patent. Thus, whether Cipla infringes claims 1-8 of the '587 Patent depends on whether Cipla's ANDA Product satisfies the additional language in claim 1. In my opinion, Cipla's ANDA Product satisfies that limitation. Thus, in my opinion, Cipla's ANDA Product satisfies every limitation of claims 1-8 of the '587 Patent.

178. I have been informed that the parties have agreed that the term "protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" should be constructed to mean "guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter". I have applied that

construction in performing my analysis.

179. As explained above, Cipla's ANDA Product comprises a series of nine inner wall canister support formations or support rails, seven of which consist of what Cipla refers to as "ribs" and two of which consist of what Cipla refers to as "mounting tabs." As I explain in connection with claim 1 of the '289 Patent, these inner wall canister support formations prevent Cipla's medicament canister from rocking within the inhaler body. *See, e.g.*, *supra* Sections VIII.A.1.e, VIII.A.1.g ('289 Patent, Claim 1).

180. The arrangement of Cipla's inner wall canister support formations support this conclusion. As I explain in connection with claim 1 of the '289 Patent, the Asserted Patents describe that, in certain embodiments, an inner wall canister support formation, the actuation member, and the central outlet port lie on a common plane to prevent the medicament canister from rocking in the direction of the actuation member. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7; *supra* Sections VIII.A.1.e, VIII.A.1.g ('289 Patent, Claim 1). That Cipla's inner wall canister support formations, actuation member, and central outlet port are similarly positioned provides additional support for the conclusion that Cipla's arrangement protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

181. Exhibit B describes experiments comparing samples Cipla's ANDA Product with and without Cipla's inner wall canister support formations. In those experiments, I measured the extent to which Cipla's medicament canister could be rocked in samples of Cipla's ANDA Product, in terms of maximum side-to-side movement, maximum front-to-back movement, and maximum angle. I then removed Cipla's inner wall canister support formations from those samples and performed the same measurements. Below, I reproduce the results of those

experiments.

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

		Mean ± Standard Deviation
Canister/Valve Assembly Height (mm), (n = 5)		61.58 ± 0.01
Maximum Side-to-Side Movement (mm)	**As Supplied** (n = 10)	1.93 ± 0.05
	Ribs Removed (n = 10)	3.4 ± 0.2
Maximum Front-to-Back Movement (mm)	**As Supplied** (n = 5)	2.15 ± 0.01
	Ribs Removed (n = 5)	3.11 ± 0.02
Maximum Angle to Normal (°)	**As Supplied** (n = 15)	0.9 ± 0.1
	Ribs Removed (n = 15)	1.5 ± 0.1

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

		Mean ± Standard Deviation
Canister/Valve Assembly Height (mm), (n = 5)		61.46 ± 0.01
Maximum Side-to-Side Movement (mm)	**As Supplied** (n = 10)	2.00 ± 0.02
	Ribs Removed (n = 10)	3.01 ± 0.01
Maximum Front-to-Back Movement (mm)	**As Supplied** (n = 5)	2.37 ± 0.06
	Ribs Removed (n = 5)	3.12 ± 0.01
Maximum Angle to	**As Supplied**	1.0 ± 0.1

Normal (°)	(n = 15)	
	Ribs Removed (n = 15)	1.4 ± 0.1

As the results demonstrate, the arrangement of Cipla's inner wall canister support formations prevent Cipla's medicament canister from rocking, in terms of maximum side-to-side movement, maximum front-to-back movement, and maximum angle.

182. [redacted]

183. Cipla contends that it does not infringe these claims because, purportedly, in Cipla's ANDA Product, the "structural arrangement of the alleged canister support formations, alleged central outlet port, and alleged actuation member does not perform the function of 'protect[ing] against unwanted actuations of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.' The Cipla ANDA Product is not susceptible to unwanted actuation through rocking." Cipla Non-Infringement Contentions, '587 Patent, Claim 1. I disagree. As I explain above, the arrangement of Cipla's inner wall canister support formations, actuation member, and central outlet port performs this function. *See, e.g.*,

Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings); Exhibit B.

184. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of these claims. For example, physical inspection confirms that Cipla's ANDA Product comprises (a) inner wall canister support formations (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs"), (b) an actuation member, and a central outlet port; (2) Cipla's inner wall canister support formations extend inwardly from the main surface of the inner wall of the medicament canister; (3) with respect to Cipla's ANDA Product, it is possible to construct multiple common planes through each of an inner wall canister support formation, an actuation member, and the central outlet port; and (4) the arrangement of Cipla's inner wall canister support formations, actuation member, and central outlet port reduce rocking of the medicament canister and increase the amount of force required to cause Cipla's dose counter to actuate. *See, e.g.*, Cipla Samples.

185. Cipla also contends that it does not infringe these claims for the same reasons that it contends that it does not infringe claims 1-8 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '587 Patent, Claims 1-8. I disagree for the reasons stated above in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1-VIII.A.8 ('289 Patent, Claims 1-8).

2. '587 Patent, Claim 11

186. Claim 11 of the '587 Patent recites: "The inhaler as claimed in claim 1 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the actuation member and the central outlet port lie in a common plane coincident with longitudinal axis X." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

187. In my opinion, Cipla's ANDA Product is an inhaler as claimed in claim 1, as

explained above. *See, e.g.*, *supra* Section VIII.B.1 ('587 Patent, Claim 1). The evidence cited in connection with claim 1 of the '289 Patent further shows that, with respect to Cipla's ANDA Product, it is possible to construct multiple common planes through multiple inner wall canister support formations, the central outlet port, and the aperture through which Cipla's actuator extends. *See, e.g.*, *supra* Section VIII.A.1.g ('289 Patent, Claim 1). Thus, Cipla's ANDA Product further satisfies the limitation "wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X."

188. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that, with respect to Cipla's ANDA Product, it is possible to construct multiple common planes through multiple inner wall canister support formations, the central outlet port, and the aperture through which Cipla's actuator extends. *See, e.g.*, Cipla Samples.

189. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent. *See* Cipla Non-Infringement Contentions,'587 Patent, Claim 11. I disagree for the reasons stated in connection with that claim. *See, e.g.*, ('289 Patent, Claim 1).

3. '587 Patent, Claim 12

190. Claims 1 and 12 of the '587 Patent are identical, except for the following **underlined** language:

'587 Patent, Claim 1	**'587 Patent, Claim 12**
1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable	1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable

relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.**	relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose counter errors by reducing rocking of the medicament canister towards or away the actuation member.**

Whereas claim 1 of the '587 Patent requires the inner wall canister support formation, the actuation member, and the central outlet port to lie in a common plane coincident with the longitudinal axis X, "such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler," claim 12 requires those components to lie in a common plane "such that the first inner wall canister support formation protects against dose counter errors by reducing rocking of the medicament canister towards or away the actuation member." Thus, whether Cipla's ANDA Product satisfies every limitation of claim 12 depends on whether it satisfies that language.

191. In my opinion, Cipla's ANDA Product satisfies this limitation. Because the inner wall canister support formations in Cipla's ANDA Product (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs") are adjacent to the medicament canister and line in a common plane with the actuation member (i.e., one or more of the castellations on the top of what Cipla refers to as an "indexer"), they protect against dose counter errors (i.e., unwanted actuation of the dose counter) by reducing rocking of the medicament canister from rocking both towards and away from the actuation member. When the medicament canister rocks towards the actuation member, the medicament canister comes into contact with the top of the inner wall canister support formation, preventing it from rocking further. When the medicament canister rocks away from the actuation member, the medicament canister comes into contact with a lower portion of the inner wall canister support formation. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings); Exhibit B.

192. Cipla contends that it does not infringe this claim because, purportedly, in Cipla's ANDA Product, the arrangement of Cipla's inner wall canister support formations, actuation member, and central outlet port "does not perform the function of 'protect[ing] against dose count errors by reducing rocking of the medicament canister relative to the main body of the inhaler.' The inhaler used in Plaintiff's ANDA Product is not susceptible to count errors through rocking." I disagree. As I explain above, the arrangement of Cipla's inner wall canister support formations, actuation member, and central outlet port performs this function. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings); Exhibit B.

193. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA

Product satisfies the limitations of this claim. For example, physical inspection confirms that Cipla's inner wall canister formations prevent Cipla's medicament canister from rocking towards and away from the actuation member. *See, e.g.*, Cipla Samples.

194. Cipla also contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '587 Patent, Claim 12. I disagree for the reasons stated in connection with that claim. *See, e.g.*, *supra* Sections VIII.A.1 ('289 Patent, Claim 1).

4. '587 Patent, Claim 13

195. Claim 13 of the '587 Patent recites as follows:

> 13. An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
> wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

196. Claims 1 and 3 of the '289 Patent recite every limitation of claim 13 of the '587 Patent. In my opinion, Cipla's ANDA Product satisfies each of those limitations. *See, e.g.*, *supra* Sections VIII.A.1, VIII.A.3 ('289 Patent, Claims 1, 3). Thus, in my opinion, Cipla's ANDA Product satisfies every limitation of claim 13 of the '587 Patent.

197. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim, including for the reasons stated in connection with

claims 1 and 3 of the '289 Patent. *See, e.g.*, Cipla Samples.

198. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1 and 3 of the '289 Patent. *See* Cipla Non-Infringement Contentions, '587 Patent, Claim 13. I disagree for the reasons stated in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.A.3 ('289 Patent, Claims 1, 3).

5. '587 Patent, Claims 14-19

199. Claims 14-19 of the '587 Patent depend directly or indirectly from claim 13 and recite additional limitations that are identical to those recited in claims 2, 4-8 of the '289 Patent and claims 2, 4-8 of the '587 Patent. In my opinion, Cipla's ANDA Product satisfies every limitation of these claims.

200. In my opinion, Cipla's ANDA Product is an inhaler as claimed in claim 13 of the '587 Patent, as explained above. *See, e.g.*, *supra* Section VIII.B.4 ('587 Patent, Claim 13). As stated in connection with claims 2, 4-8 of the '289 Patent and claims 2, 4-8 of the '587 Patent, Cipla's ANDA Product further satisfies the limitations of those claims. *See, e.g.*, *supra* Sections VIII.A.2, VIII.A.4-VIII.A.8, VIII.B.1 ('289 Patent, Claims 2, 4-8; '587 Patent, Claims 2, 4-8). Thus, in my opinion, Cipla's ANDA Product satisfies every limitation of these claims.

201. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of these claims, including for the reasons stated in connection with claims 1-2, 4-8 of the '289 Patent and 1-2, 4-8 of the '587 Patent. *See, e.g.*, Cipla Samples.

202. Cipla contends that it does not infringe these claims for the same reasons that it contends that it does not infringe claims 1-2 and 4-8 of the '289 Patent and claims 1-2, and 4-8 of the '587 Patent. *See* Cipla Non-Infringement Contentions,'587 Patent, Claims 14-19. I disagree for the reasons stated in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1-VIII.A.2, VIII.A.4-VIII.A.8, VIII.B.1. ('289 Patent, Claims 1-2, 4-8; '587 Patent, Claims 1-2, 4-

8).

6. '587 Patent, Claim 20

203. Claim 20 of the '587 Patent recites: "The inhaler as claimed in claim 15, wherein a width dimension of the support rail is not constant, and the width dimension is greatest at the location where the support rail is closest to the aperture." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

204. I have been informed that the parties have proposed different constructions for the term "aperture." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "an opening or open space: hole." I have been informed that Defendants propose that the term should be construed to mean "hole." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

205. In my opinion, Cipla's ANDA Product is an inhaler as claimed in claim 15 of the '587 Patent, as explained above. *See, e.g.*, *supra* Section VIII.B.5 ('587 Patent, Claims 15). As explained in connection with claim 1 of the '289 Patent, Cipla's ANDA Product further comprises a series of support rails (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs") and an aperture. *See, e.g.*, *supra* Sections VIII.A.3-VIII.A.4 ('289 Patent, Claims 1). As depicted below, Cipla's support rails have width dimensions that are not constant, and several of Cipla's support rails have width dimensions that are greatest at the location where the support rail is closest to the aperture.

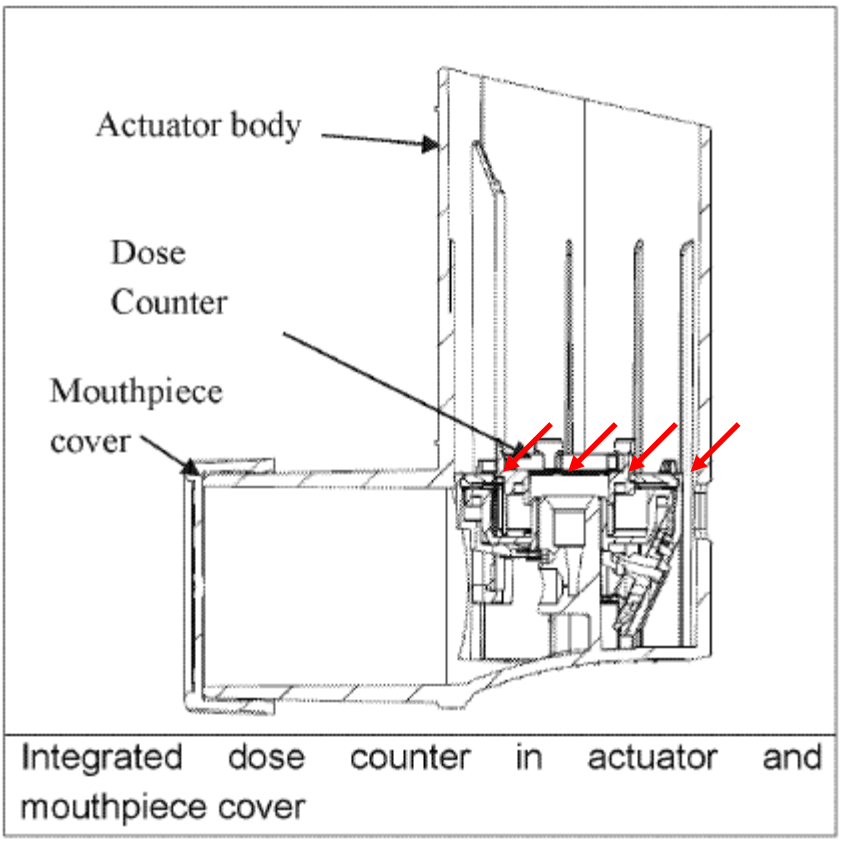


Figure 41: Actuator with Integrated Dose counter

See, e.g., CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); *see also* Cipla Samples; CIPLA-BDI_0803837-38 (Design Drawings).

206. Cipla contends that it does not infringe this claim because, purportedly, Cipla's ANDA Product "does not have a support rail where the width is not constant. CIPLA-BDI_0156595; CIPLA-BDI_0156597; CIPLA_P_000001-50; CIPLA-BDI_0156579; and CIPLA-BDI_0004411-705." I have reviewed the materials Cipla cites, and I disagree. As I explain above, Cipla's support rails satisfy this limitation. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

207. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1)

Cipla's ANDA Product comprises a series of support rails (seven of which Cipla refers to as "ribs" and two of which Cipla refers to as "mounting tabs") and an aperture; and (2) several of Cipla's support rails have width dimensions that are greatest at the location where the support rail is closest to the aperture. *See, e.g.*, Cipla Samples.

208. Cipla also contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 13 and 15 of the '587 Patent. *See* Cipla Non-Infringement Contentions,'587 Patent, Claim 20. I disagree for the reasons stated in connection with those claims. *See, e.g.*, *supra* Sections VIII.B.4-VIII.B.5 ('587 Patent, Claims 13, 15).

7. '587 Patent, Claim 21

209. Claim 21 of the '587 Patent recites: "The inhaler as claimed in claim 13, wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

210. In my opinion, Cipla's ANDA Product is an inhaler as claimed in claim 13 of the '587 Patent, as explained above. *See, e.g.*, *supra* Section VIII.B.4 ('587 Patent, Claim 13). As explained in connection with claim 1 of the '289 Patent, Cipla's ANDA Product further satisfies the limitation "wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port." *See, e.g.*, *supra* Section VIII.A.1.g ('289 Patent, Claim 1). Thus, in my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

211. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA

Product satisfies the limitations of this claim, including for the reasons stated in connection with claim 1 of the '289 Patent. *See, e.g.*, Cipla Samples.

212. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent and claim 13 of the '587 Patent. *See* Cipla Non-Infringement Contentions,'587 Patent, Claim 21. I disagree for the reasons stated in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.B.4 ('289 Patent, Claim 1; '587 Patent, Claim 13).

8. '587 Patent, Claim 22

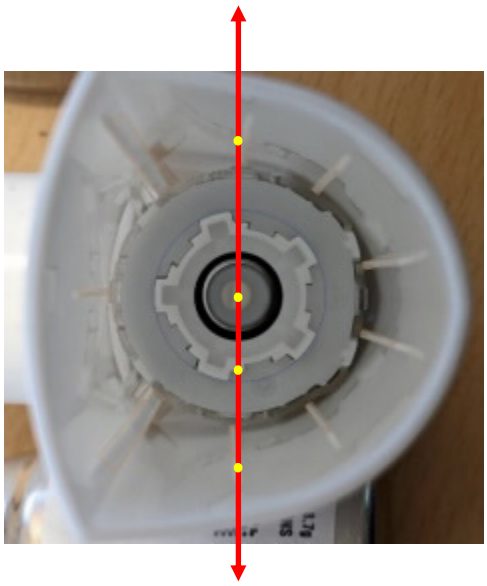
213. Claim 22 of the '587 Patent recites: "The inhaler as claimed in claim 21 further comprising a second inner wall canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

214. In my opinion, Cipla's ANDA Product is an inhaler as claimed in claim 21, as explained above. *See, e.g.*, *supra* Section VIII.B.7 ('587 Patent, Claim 21). The evidence cited in connection with claim 1 of the '289 Patent further shows that, with respect to Cipla's ANDA Product, it is possible to construct multiple common planes through multiple inner wall canister support formations, the central outlet port, and the aperture through which Cipla's actuator extends. *See, e.g.*, *supra* Sections VIII.A.1.g, VIII.B.3 ('289 Patent, Claim 1; '587 Patent, Claim 12). Thus, in my opinion, Cipla's ANDA Product further satisfies the limitation "wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X."

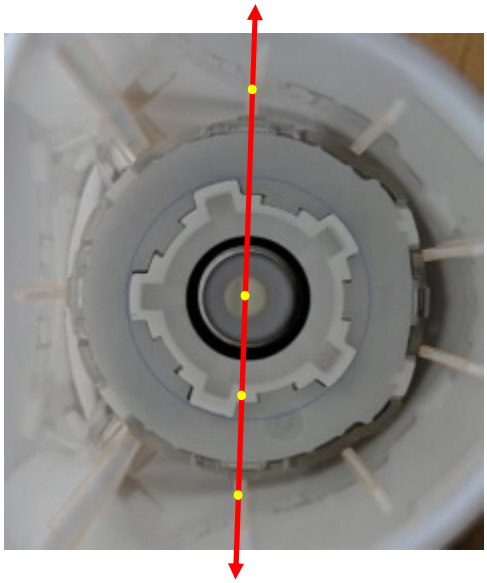
215. The following top-down photographs of photographs of samples of Cipla's ANDA Product, 40 mcg (Lot IB81152 (exp. 07/2020)) and 80 mcg (Lot IB90362 (exp.

09/2020)) further show that Cipla's ANDA Product satisfies this limitation. Again, the common planes depicted in these figures are merely illustrative; and it is possible to construct multiple common planes passing through the relevant components of Cipla's ANDA Product.

Cipla's ANDA Product, 40 mcg



Cipla's ANDA Product, 80 mcg



216. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA

Product satisfies the limitations of this claim, including for the reasons stated in connection with claim 1 of the '289 Patent and claims 13 and 21 of the '587 Patent. *See, e.g.*, Cipla Samples.

217. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '289 Patent and claims 13 and 21 of the '587 Patent. *See* Cipla Non-Infringement Contentions, '587 Patent, Claim 22. I disagree for the reasons stated in connection with those claims. *See, e.g.*, *supra* Sections VIII.A.1, VIII.B.4, VIII.B.7 ('289 Patent, Claim 1; '587 Patent, Claims 13, 21).

C. U.S. Patent No. 10,861,156 ('156 Patent)

1. '156 Patent, Claim 1

218. In my opinion, Cipla's ANDA Product satisfies every limitation of claim 1 of the '156 Patent.

219. Claim 1 recites as follows:

> 1. A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
> a ratchet wheel having a plurality of circumferentially spaced teeth,
> an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
> a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
> a dosage indicator associated with the count pawl,
> wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
> wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration,
> the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the

count
configuration, whereby the dosage indicator has indicated a count,
wherein, in the canister fire configuration, the actuator
pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

I address each limitation of this claim below.

a. "A Dose Counter for a Metered Dose Inhaler"

220. In my opinion, Cipla's ANDA Product comprises "a dose counter for a metered dose inhaler." *See, e.g.*, *supra* Sections VIII.A.1.a, VIII.A.1.d ('289 Patent, Claim 1). Physical inspection confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla Samples. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 1.

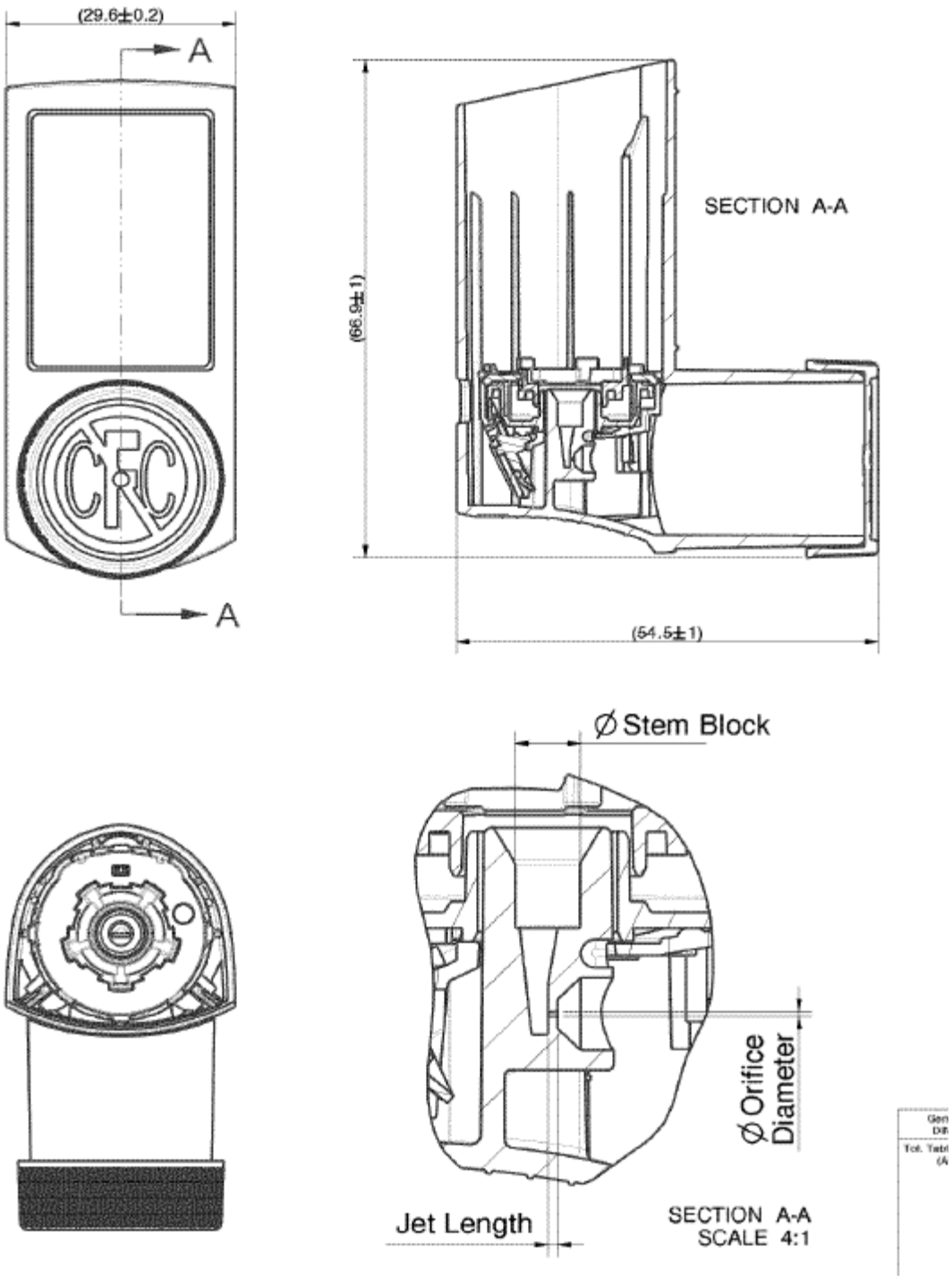
b. "Having a Body Arranged to Retain a Medicament Canister of Predetermined Configuration for Movement of the Medicament Canister Relative Thereto"

221. In my opinion, Cipla's ANDA Product has an inhaler body (which Cipla refers to as an "actuator"). *See, e.g.*, *supra* Section VIII.A.1.b ('289 Patent, Claim 1). Cipla's inhaler body is further is "arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto."

222. First, Cipla's inhaler is arranged to retain a medicament canister of predetermined configuration. That is, Cipla's inhaler body is not physically compatible with all medicament canisters; it is compatible only with certain medicament canisters. To be physically compatible with Cipla's inhaler body, a medicament canister must share the same general physical shape and dimensions (e.g., length, width, height, etc.) as Cipla's medicament canister. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

223. As the following design drawing illustrates, Cipla's inhaler body has a number of

design features, including, among others, the overall shape and dimensions (length, width, height) of the inhaler body, the shape and dimensions of the valve stem block, and the presence, shape and dimensions of the support rails running along the side of the inhaler body, that make it compatible only with certain medicament canisters.



See, e.g., CIPLA-BDI_0803837-38 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156595, at -595, -597 (Photographs).

224. Second, Cipla's inhaler body is arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative to the inhaler body. As explained above, Cipla's medicament canister is moveable relative to its inhaler body. *See, e.g.*, *supra* Section VIII.A.1.c ('289 Patent, Claim 1). This is because Cipla's inhaler body and medicament canister are physical compatible. If this were not the case, for example, because Cipla's inhaler body or support rails were too small, the medicament canister would not be able to move. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

225. That Cipla's inhaler body is arranged to retain a medicament canister of predetermined configuration is further confirmed by the fact that Cipla's medicament canister cannot be inserted into its inhaler body arbitrarily. Rather, there is only one way to insert Cipla's medicament canister into Cipla's inhaler body. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0803837-38 (Design Drawings).

226. [redacted]

227. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that (1) Cipla's inhaler body is compatible with Cipla's medicament canister, but not others that lack the same general shape and dimensions; and (2) Cipla's medicament canister is moveable relative to its inhaler body. *See, e.g.*, Cipla Samples.

228. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions,'156 Patent, Claim 1.

c. "The Medicament Canister Containing an Active Drug"

229. In my opinion, the Cipla's medicament canister contains "an active drug" (i.e., beclomethasone dipropionate). *See, e.g.*, Cipla Samples; CIPLA-BDI_0000635 ("Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg and 80 mcg"); CIPLA-BDI_0155972, at -982 (Proposed Labeling) ("The active component of beclomethasone dipropionate HFA, inhalation aerosol 40 mcg and beclomethasone dipropionate HFA, inhalation aerosol 80 mcg is beclomethasone dipropionate, USP, a corticosteroid having the chemical name 9-chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate."); CIPLA-BDI_0001675, at -681 (Quality Overall Summary). Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla Samples. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions,'156 Patent, Claim 1.

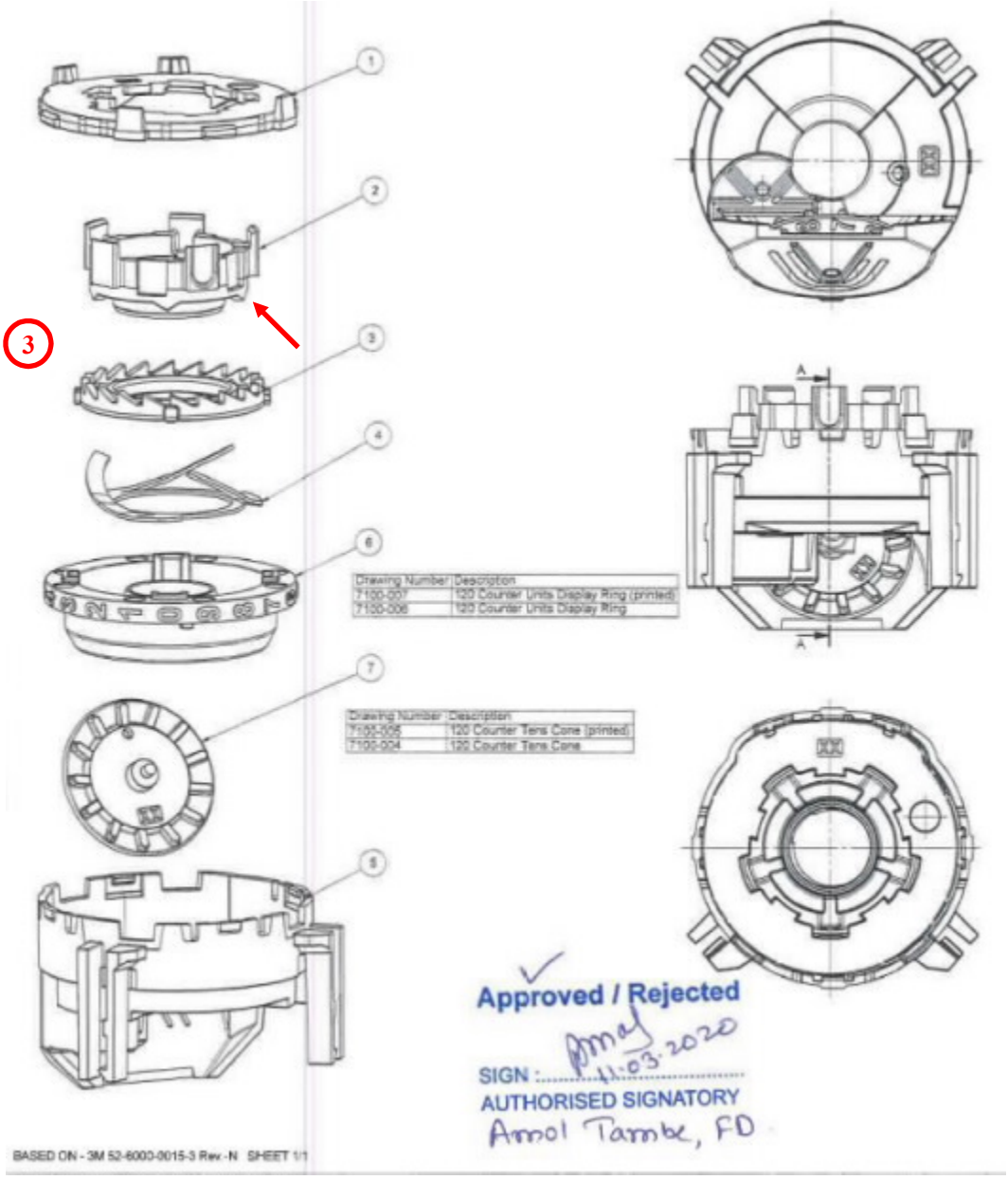
d. "The Dose Counter Comprising"

1) "A Ratchet Wheel Having a Plurality of Circumferentially Spaced Teeth"

230. In my opinion, Cipla's dose counter comprises "a ratchet wheel having a plurality of circumferentially spaced teeth." I have been informed that the parties have agreed that the term "ratchet wheel" should be construed to mean "a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl." I have applied this construction in performing my analysis.

231. Cipla's dose counter comprises a ratchet wheel (i.e., what Cipla refers to as a "units teeth ring") (3), which is arranged to engage with the triangular protrusions on the bottom

of Cipla's actuator (i.e., what Cipla refers to as an "indexer") (arrow), which correspond to the claimed actuator pawl and count pawl. *See, e.g.*, *infra* Sections VIII.C.1.d.2)-VIII.C.1.d.3) ('156 Patent, Claim 1).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

232. As illustrated above, Cipla's units teeth ring is a wheel that has a plurality of circumferentially spaced teeth. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

233. [redacted]

234. Cipla contends that it does not infringe this limitation, purportedly, because Cipla's ANDA Product "Cipla ANDA Product does not have a 'ratchet wheel.' CIPLA-BDI_0156595; CIPLA- BDI_0156597; CIPLA_P_000001-50; CIPLA-BDI_0156579; and CIPLA-BDI_0004411-705." Cipla further contends that it does not infringe this claim because Cipla's ANDA Product does not comprise other "structural limitations" recited in the claim, including a "first tooth," a "second tooth," an "actuator pawl," and a "count pawl." I have reviewed the materials Cipla cites, and I disagree. As explained above, Cipla's units teeth ring satisfies all of the requirements of the ratchet wheel, i.e., it is a wheel having a plurality of circumferentially spaced teeth, and it is arranged to engage with the triangular protrusions on the

bottom of Cipla's indexer, which correspond to the claimed actuator pawl and count pawl. I address Cipla's contentions regarding the other limitations of this claim below. *See, e.g.*, *infra* Sections VIII.C.1.d.2)-VIII.C.1.d.3) ('156 Patent, Claim 1).

235. The '156 Patent confirms this analysis. The '156 Patent describes that, in certain embodiments, the dose counter comprises, among other components, an actuator pawl (80), ratchet wheel (96), and count pawl (138). When the user presses down on the medicament canister, the actuator pawl (90), pulls down on one of the teeth of the ratchet wheel (96), which causes the ratchet wheel to rotate (96). As the ratchet wheel (96) rotates, it engages with the count pawl (136). *See, e.g.*, '156 Patent, 4:34-45, 13:42-15:33, Figs. 10A-10F.

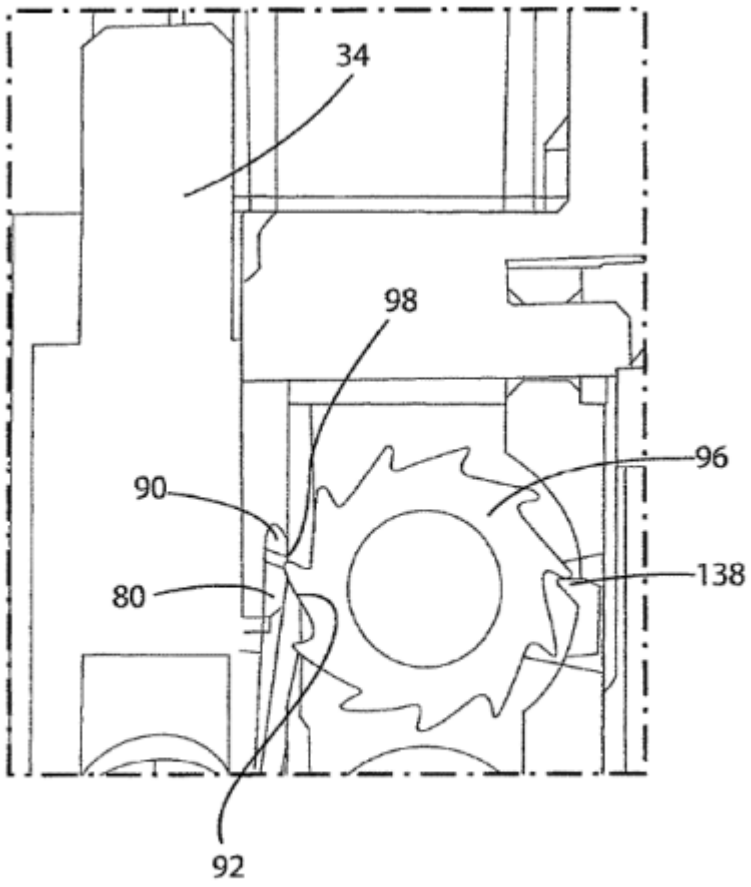


FIG. 10C

See, e.g., '156 Patent, Fig. 10C.

236. As in the above embodiments, when a patient presses down on Cipla's medicament canister, one or more of the triangular protrusions on the bottom of Cipla's indexer, which correspond to the claimed actuator pawl, push down on one or more of the inner teeth of Cipla's units teeth ring, causing Cipla's units teeth ring to rotate. As Cipla's units teeth ring rotates, another one or more of the inner teeth of Cipla's units teeth ring engages with another one or more of the triangular protrusions on the bottom of Cipla's indexer, which correspond to the claimed count pawl. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

237. In my opinion, to the extent that Cipla's units teeth ring does not literally satisfy the requirements of a ratchet wheel, it satisfies those requirements under the doctrine of equivalents. As described above, Cipla's units teeth ring is insubstantially different from the claimed ratchet wheel. Both are wheel-like structures that have a plurality of circumferentially spaced teeth and engage with the triangular protrusions on the bottom of Cipla's indexer, which correspond to the claimed count pawl and actuator pawl. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

238. Alternatively, Cipla's units teeth ring and the claimed ratchet wheel perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of transforming the linear movement of the component that corresponds to the actuator pawl into rotational motion, by way of providing a wheel-like structure with teeth, to achieve the same result of engaging with the component that corresponds to the count pawl. *See,*

e.g., Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

239. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that one of the triangular protrusions of Cipla's indexer engages with an inner tooth of Cipla's units teeth ring, which causes Cipla's units teeth ring to rotate, which causes another of the inner teeth of Cipla's units teeth ring to engage with another of the triangular protrusions on the bottom of Cipla's indexer. *See, e.g.*, Cipla Samples.

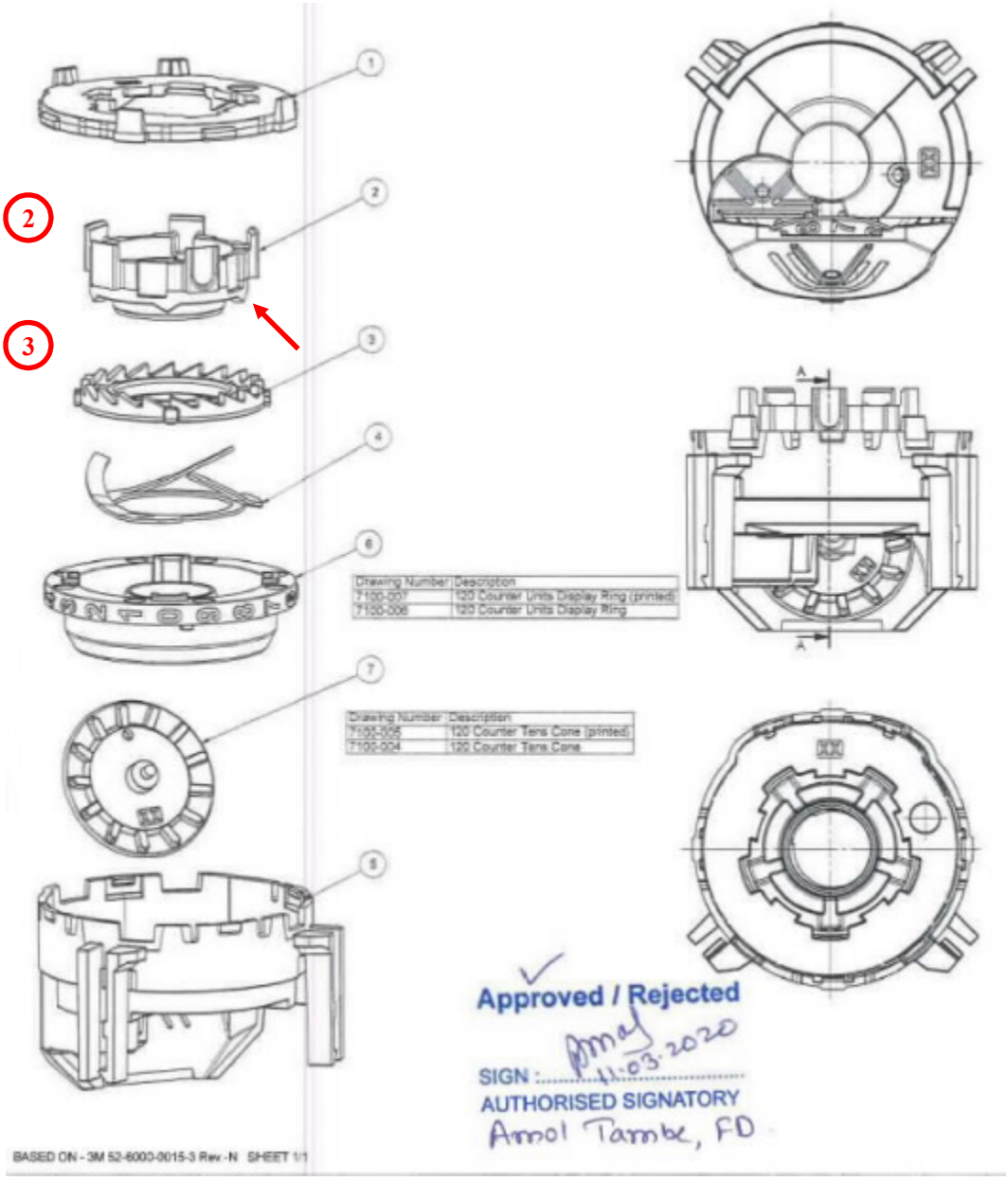
2) "An Actuator Comprising an Actuator Pawl Arranged to Engage with a First Tooth of the Ratchet Wheel Wherein the Actuator Can Be Driven in Response to Canister Motion to Drive the Ratchet Wheel to Rotate"

240. In my opinion, Cipla's dose counter comprises "an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel wherein the actuator can be driven in response to drive the ratchet wheel to rotate."

241. I have been informed that the parties have agreed that the term "actuator" should be construed to mean "a structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component"; that the term "actuator pawl" should be construed to mean "a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel"; and that the term "ratchet wheel" should be construed to mean "a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl." I have applied those constructions in performing my analysis.

242. Cipla's dose counter comprises an actuator (i.e., what Cipla's refers to as an "indexer" (2)), which further comprises an actuator pawl consisting of one or more of the

triangular protrusions on the bottom of the actuator (arrow). As explained above, Cipla's dose counter also comprises a ratchet wheel (i.e., what Cipla refers to as a "units teeth ring" (3)). *See, e.g.*, *supra* Section VIII.C.1.d.1) ('156 Patent, Claim 1).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

243. Above, I explain why Cipla's ratchet wheel satisfies the requirements of a ratchet wheel. *See, e.g.*, *supra* Section VIII.C.1.d.1) ('156 Patent, Claim 1).

244. In my opinion, Cipla's ANDA Product satisfies the remaining requirements of this limitation, as the parties agree that it should be construed. Specifically, (1) Cipla's actuator is a structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter (e.g., Cipla's ratchet wheel), and effectuates movement of at least one additional dose counter component; (2) Cipla's actuator pawl is a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel; and (3) Cipla's actuator can be drive in response to canister motion to drive the ratchet wheel to rotate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

245. In particular, when a patient presses down on Cipla's medicament canister, the medicament canister pushes down on Cipla's actuator, causing it to move downward. As Cipla's actuator moves downward, a first inner tooth of Cipla's units teeth ring engages with one or more of the triangular protrusions on the bottom of Cipla's actuator, causing the units teeth ring to rotate. As the units teeth ring rotates, a second inner tooth of the units teeth ring engages with one or more of the triangular protrusions on the bottom of Cipla's indexer. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

246. [redacted]

[redacted]

247. The '156 Patent confirms this analysis. The '156 Patent describes that, in certain embodiments, the dose counter comprises, among other components, an actuator pawl (80), ratchet wheel (96), and count pawl (138). As explained above, when the user presses down on the medicament canister, the actuator pawl (90), pulls down on one of the teeth of the ratchet wheel (96), which causes the ratchet wheel to rotate (96). As the ratchet wheel (96) rotates, it engages with the count pawl (136). *See, e.g.*, '156 Patent, 4:34-45, 13:42-15:33, Figs. 10A-10F.

248. As in those embodiments, when a patient presses down on Cipla's medicament canister, one or more of the triangular protrusions on the bottom of Cipla's indexer, which correspond to the claimed actuator pawl, push down on one or more of the inner teeth of Cipla's units teeth ring, causing Cipla's units teeth ring to rotate. As it rotates, another one or more of the inner teeth of Cipla's units teeth ring engages with another one or more of the triangular protrusions on the bottom of Cipla's indexer, which correspond to the claimed count pawl. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

249. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product "does not have an 'actuator pawl' and therefore also lacks the claimed 'actuator.' *See* CIPLA-BDI_0156595; CIPLA-BDI_0156597; CIPLA_P_000001-50; CIPLA-BDI_0156579; and CIPLA-BDI_0004411-705." I have reviewed the materials Cipla cites, and I disagree. As explained above, Cipla's ANDA Product comprises both an actuator (what Cipla refers to as an "indexer" and an "actuator pawl" (one or more of the triangular protrusions on the

bottom of Cipla's "indexer"). *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

250. Additionally, in my opinion, to the extent that Cipla's ANDA Product does not literally comprise an "actuator" or "actuator pawl," it does so under the doctrine of equivalents.

251. As described above, Cipla's indexer is insubstantially different from the claimed actuator. Both transfer the linear movement of the medicament canister to the component that corresponds to the units teeth ring, and both comprise features (in the case of Cipla's indexer, the triangular protrusions at the bottom) that engage with a first tooth of the component that corresponds to the ratchet wheel, causing the ratchet wheel to rotate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

252. Alternatively, both perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of transferring the linear movement of the medicament canister to the component that corresponds to the units teeth ring, by way of providing a feature capable of engaging with a first tooth of the component that corresponds to the ratchet wheel (in the case of Cipla's indexer, the triangular protrusions at the bottom), to obtain the result of causing the units teeth ring to rotate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

253. Additionally, as described above, the triangular protrusions on the bottom of Cipla's indexer are insubstantially different from the claimed actuator pawl. Both transfer the linear movement of the actuator to the component that corresponds to the ratchet wheel and

engage with the ratchet wheel, causing the ratchet wheel to rotate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

254. Alternatively, the triangular protrusions on the bottom of Cipla's indexer and the claimed actuator pawl perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of transferring the linear movement of the component that corresponds to actuator to the component that corresponds to the ratchet wheel, by way of providing a structure capable of engaging with the teeth of the ratchet wheel, to achieve the same result of causing the ratchet wheel to rotate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

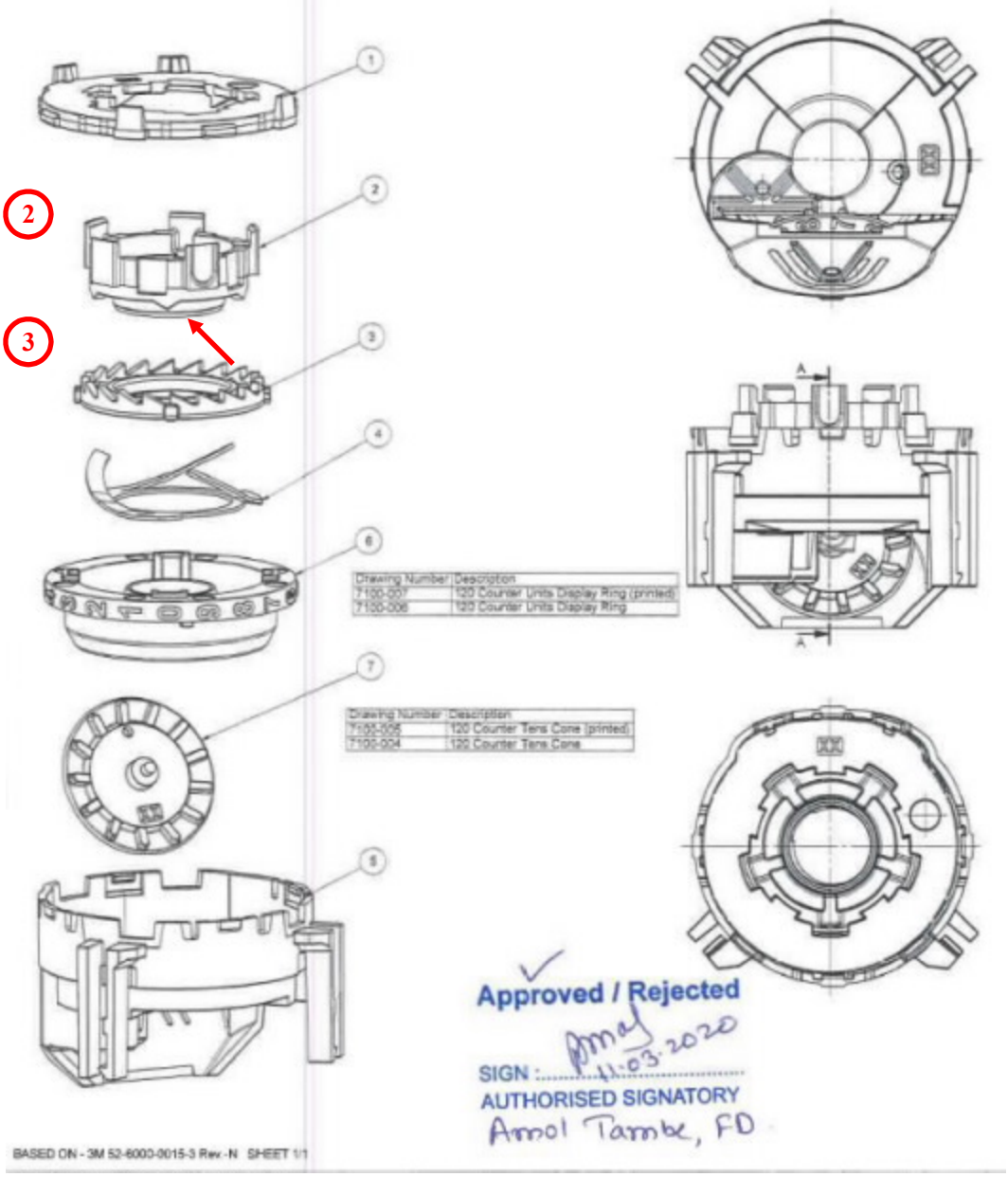
255. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that one of the triangular protrusions of Cipla's indexer engages with an inner tooth of Cipla's units teeth ring, which causes Cipla's units teeth ring to rotate, which causes another inner tooth of Cipla's units teeth ring to engage with another of the triangular protrusions on the bottom of Cipla's indexer. *See, e.g.*, Cipla Samples.

3) "A Count Pawl Arranged to Engage with a Second Tooth of the Ratchet Wheel, Wherein as the Ratchet Wheel is Driven by the Actuator to Rotate, the Count Pawl Rides Along a Forward Surface of the Second Tooth and Resiliently Jumps over the Second Tooth"

256. In my opinion, Cipla's dose counter comprises "a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth."

257. I have been informed that the parties have proposed different constructions for the term "count pawl." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel." I have been informed that Defendants propose that the term should be construed to mean "a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

258. Cipla's dose counter comprises an actuator (which Cipla refers to as an "indexer" (2)), and a count pawl (i.e., another one or more of the triangular protrusions on the bottom of what Cipla refers to as an "indexer") (red arrow), the latter of which is arranged to engage with a second tooth of the ratchet wheel (i.e., what Cipla refers to as a "units teeth ring" (3)).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

259. Additionally, Cipla's ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth. When a patient presses down on Cipla's medicament canister, the medicament canister

pushes down on Cipla's actuator, causing it to move downward. As Cipla's actuator moves downward, a first inner tooth of Cipla's units teeth ring engages with one or more of the triangular protrusions on the bottom of Cipla's actuator, causing the units teeth ring to rotate. As the units teeth ring rotates, a second inner tooth of the units teeth ring engages with one or more of the triangular protrusions on the bottom of Cipla's indexer, riding along and disengaging with (i.e., resiliently jumping over) that second inner tooth. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).; *supra* Sections VIII.C.1.d.1)-VIII.C.1.d.2) ('156 Patent, Claim 1). Thus, Cipla's ANDA Product satisfies this limitation under Teva's proposed construction.

260. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise a "count pawl," "ratchet wheel," or "actuator pawl," and therefore cannot satisfy the additional language in this limitation. I disagree. As I explain above, Cipla's ANDA Product comprises a count pawl (i.e., one or more of the triangular protrusions on the bottom of what Cipla refers to as an "indexer"). I address Cipla's contentions regarding the "ratchet wheel" and "actuator pawl" above. *See, e.g.*, *supra* Sections VIII.C.1.d.1)-VIII.C.1.d.2) ('156 Patent, Claim 1).

261. Additionally, even if, contrary to my opinion, Cipla's ANDA Product does not satisfy this limitation literally, it satisfies this limitation under the doctrine of equivalents. The '156 Patent describes that, in certain embodiments, the inhaler comprises an actuator pawl, ratchet wheel, and count pawl. When the patient presses down on the medicament canister, the actuator pawl pulls down on a first tooth of the ratchet wheel, which causes the ratchet wheel to rotate. The rotation of the ratchet wheel causes a second tooth of the ratchet wheel to engage

with the count pawl. *See, e.g.*, 11:39-41, 13:42-15:33, Figs. 6D, 6G, 10A-10F.

262. In my opinion, for the reasons explained above, any differences between the triangular protrusions on the bottom of Cipla's indexer and the claimed count pawl are insubstantial. In both cases, the ratchet wheel moves in response to the movement of the actuator pawl. Additionally, in both cases, the movement of the ratchet wheel further causes the count pawl to engage with the count pawl. And in both cases, the actuator pawl and the count pawl engage with different teeth of the ratchet wheel. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

263. Alternatively, the triangular protrusions on the bottom of Cipla's indexer and the claimed count pawl perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of providing a surface that engages with the ratchet wheel, by way of having a shape that is capable of engaging with a tooth of the ratchet wheel, to obtain the result of engaging with the ratchet wheel when it rotates. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

264. **Defendants' Proposed Construction.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed construction, both literally and under the doctrine of equivalents.

265. Defendants' proposed construction requires the count pawl to be "a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel." As illustrated above, Cipla's indexer has multiple triangular protrusions on its bottom, at least one of which comprises the claimed

actuator pawl and at least another of which comprises the claimed count pawl. Because those protrusions are placed at different locations around the indexer, they engage with different teeth of the ratchet wheel. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings). Moreover, as discussed above in connection with Teva's proposed construction, to the extent that Cipla's dose counter does not literally satisfy the requirement of a "count pawl," it satisfies it under the doctrine of equivalents.

266. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises a "count pawl" (i.e., another of the triangular protrusions on the bottom of what Cipla refers to as an "indexer"), and (2) as Cipla's ratchet wheel (i.e., what Cipla refers to as a "units teeth ring") is driven by the actuator (i.e., what Cipla refers to as an "indexer") to rotate, the count pawl rides along a forward surface of the second tooth of the ratchet wheel and disengages with (i.e., resiliently jumps over) that second tooth. *See, e.g.*, Cipla Samples.

4) "A Dosage Indicator Associated with the Count Pawl"

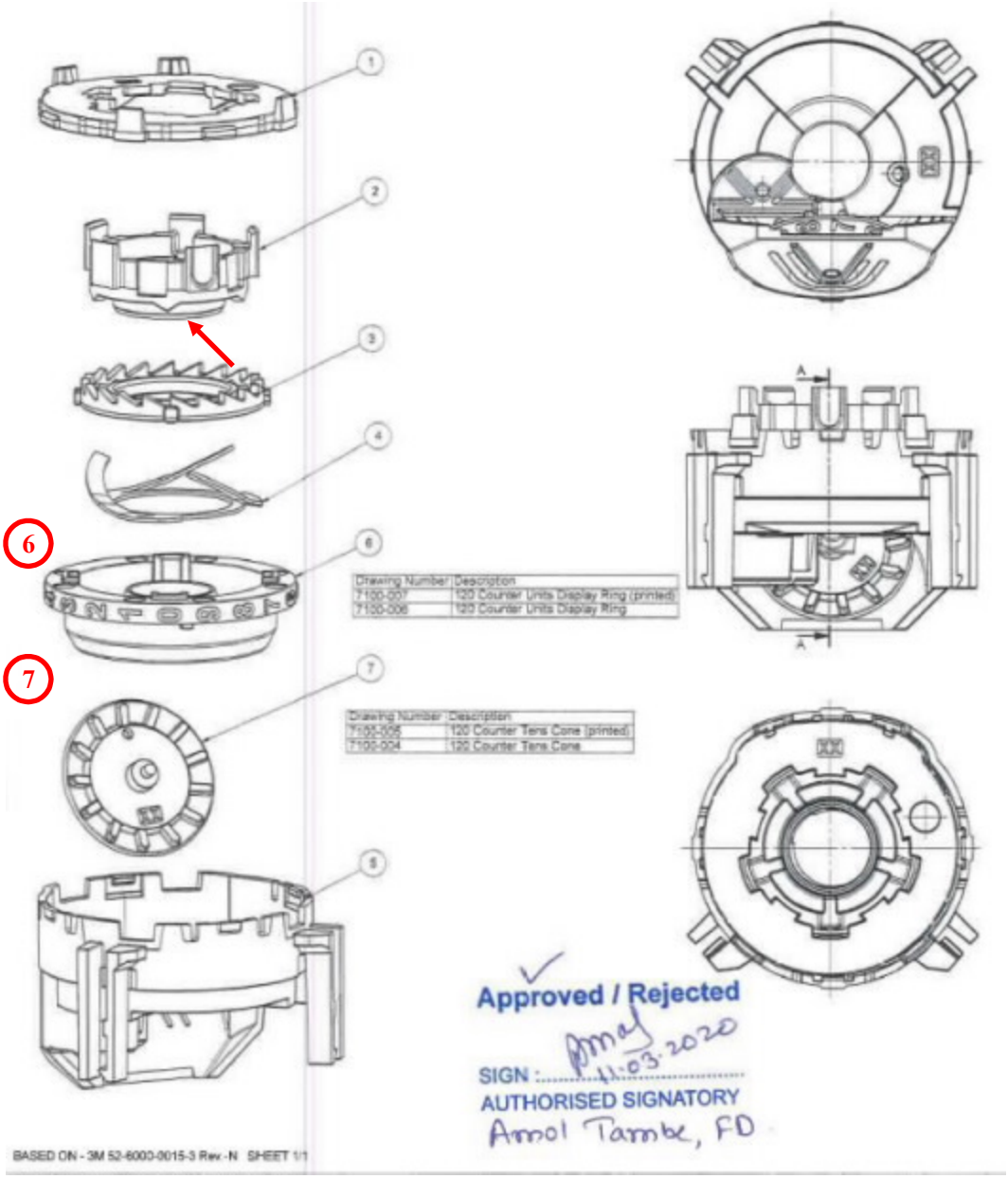
267. In my opinion, Cipla's dose counter comprises "a dosage indicator associated with a count pawl."

268. I have been informed that the parties have agreed that the term "associated with" should be construed to mean "related to." I have applied that construction in performing my analysis.

269. I have been informed that the parties have proposed different constructions for the term "count pawl." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution

history, to mean "a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel." I have been informed that Defendants propose that the term should be construed to mean "a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

270. Cipla's dose counter comprises a dosage indicator (i.e., what Cipla refers to as a "units display ring" (6) and/or "tens cone" (7)), which is associated with a count pawl (i.e., one or more of the triangular protrusions on the bottom of what Cipla refers to as an "indexer") (red arrow).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

271. In my opinion, Cipla's ANDA Product comprises a number of components, any one of which satisfies the requirements of the claimed dosage indicator: (1) Cipla's units display ring; (2) Cipla's tens cone; and (3) Cipla's units display ring and tens cone. Both individually

and collectively, each of those components provides an indication of the number of doses remaining. As their names suggest, Cipla's units display ring indicates the units (i.e., ones) digit of the number of doses remaining, and the tens cone indicates the tens digit of the number of doses remaining. Thus, at any number of doses remaining, Cipla's units display ring and tens cone collectively display the number of doses remaining. When fewer than ten doses remain, the units display ring also individually displays the number of doses remaining. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings).

272. In my opinion, each of components in Cipla's ANDA Product that constitutes the claimed dosage indicator (i.e., Cipla's units display ring and/or tens cone) is associated with (i.e., related to) the count pawl. Cipla's count pawl causes Cipla's units teeth ring to rotate, which further causes Cipla's units display ring and tens cone to rotate. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings); *supra* Sections VIII.C.1.d.1)-VIII.C.1.d.3) ('156 Patent, Claim 1). Thus, Cipla's ANDA Product satisfies this limitation under Teva's proposed construction.

273. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that (1) Cipla's units display ring and tens cone, individually and collectively, provide an indication of the number of doses remaining; (2) Cipla's units display ring and units teeth ring are associated with a count pawl (i.e., one or more of the triangular protrusions of Cipla's indexer); and (3) when Cipla's actuator pawl (i.e., one or more of the triangular protrusions of Cipla's indexer) engages with an inner tooth of Cipla's units teeth ring, it causes Cipla's units teeth ring to rotate, which causes

another inner tooth of Cipla's units teeth ring to engage with another of the triangular protrusions on the bottom of Cipla's indexer. *See, e.g.*, Cipla Samples.

274. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise a "count pawl." *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 1. I disagree for the reasons stated in connection with that limitation. *See, e.g.*, *supra* Section VIII.C.1.d.3) ('156 Patent, Claim 1).

e. "Wherein the Actuator Is Arranged to Define a First Reset Position in Which the Actuator Pawl Is Brought into Engagement With the First Tooth"

275. In my opinion, Cipla's ANDA Product comprises a dose counter "wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth."

276. I have been informed that the parties have proposed different constructions for the term "first reset position." I have been informed that Teva has proposed that the term should be construed according to its plain and ordinary meaning in view of the claims, specification, and prosecution history, to mean "a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration." I have been informed that Defendants have proposed that the term should be construed to mean a "configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel." I have been informed that Defendants have further proposed that the term "start configuration," which does not appear in claim 1, should be construed to mean "in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel." I have not been asked to provide an opinion about which constructions are correct, and I express no opinion on that issue.

Nevertheless, in my opinion, Cipla infringes under any of the proposed constructions.

277. **Teva's Proposed Constructions.** Cipla's dose counter literally satisfies this limitation under Teva's proposed constructions. As explained above, Cipla's dose counter comprises an actuator pawl. When a patient presses down on Cipla's medicament canister, the medicament canister presses down on what Cipla refers to as an "indexer." Cipla's actuator pawl (i.e., one or more of the triangular protrusions on the bottom of Cipla's indexer) move downward and comes into contact with a first tooth of Cipla's ratchet wheel (i.e., what Cipla's refers to as a "units teeth ring"). *See, e.g.*, *supra* Section VIII.C.1.d ('156 Patent, Claim 1). Cipla's dose counter enters the first reset position when Cipla's actuator pawl first comes into contact with the first tooth of the ratchet wheel. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings).

278. **Defendants' Proposed Constructions.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed constructions, at a minimum, under the doctrine of equivalents.

279. First, Cipla's dose counter is arranged to define a canister start configuration in which the actuator pawl is spaced from the ratchet wheel. As explained above, Cipla's actuator pawl (i.e., one or more of the triangular protrusions on the bottom of what Cipla refers to as an "indexer") engages with Cipla's ratchet wheel (i.e., what Cipla refers to as a "units teeth ring") as a result of a patient's pressing down on Cipla's medicament canister. Thus, before the patient presses down on the medicament canister, Cipla's actuator pawl is spaced from its ratchet wheel. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings); *supra*

Section VIII.A.2 ('289 Patent, Claim 2).

280. Second, for the reasons explained above in connection with Teva's proposed constructions, Cipla's dose counter is arranged to define a first reset position, in which Cipla's actuation pawl is just engaged with a tooth of Cipla's ratchet wheel. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings).

281. Third, when Cipla's dose counter is in the first reset position, Cipla's actuator pawl is below the position that it is in when Cipla's dose counter is in the start configuration. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings).

282. In my opinion, to the extent that Cipla's ANDA Product does not literally satisfy this limitation under Defendants' proposed constructions, for example, because it does not literally satisfy the requirements that when Cipla's dose counter is in the start configuration, "the count pawl is engaged with a tooth of the ratchet wheel" or that when Cipla's dose counter is in the first reset position, "the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration," Cipla's ANDA Product satisfies this limitation under the doctrine of equivalents.

283. The '156 Patent uses the terms "start configuration" and "first reset position" as reference points, for describing the actuator pawl at certain times during the operation of various embodiments. Specifically, it uses the term "start configuration" to refer to the point before the patient presses down on the medicament canister, when the actuator pawl is spaced from the ratchet wheel; it uses the term "first reset position" to refer to the point when the actuator pawl engages with a first tooth of the ratchet wheel. *See, e.g.*, '156 Patent, 5:39-65 ("The actuator and

incremental output member may be arranged to provide a start configuration at which the actuator is spaced from the ratchet output member, a reset configuration at which the actuator is brought into engagement with the incremental output member during a canister fire sequence, and an end configuration at which the actuator disengages from the ratchet output during a canister fire sequence."), 11:39-44, 11:48-49, 14:11-15:33, 17:24-61, Figs. 9, 10A-10F, 11, 14.

284. The '156 Patent further describes that the purpose of defining these reference points is to facilitate designing and manufacturing dose counters with appropriate tolerances, to avoid under- or over-counting. *See, e.g.*, '156 Patent, 5:39-65, 11:39-44, 11:48-49, 14:11-15:33, 17:24-61 ("FIG. 14 shows a computer system 230 for designing the dose counter 36 and in particular for calculating distributions representative of average positions and standard deviations in a production series of inhalers of the start, reset, fire, count and end positions of the actuator lower side edge 98 relative to the datum plane 220 (FIG. 9) . . ."), Figs. 9, 10A-10F, 11, 14.

285. Because the '156 Patent uses the terms "start configuration" and "first reset position" to describe the actuator pawl at certain times, the POSA would understand the count pawl to be inessential to the '156 Patent's use of those terms. Accordingly, the POSA would understand that, to the extent that, in the "start configuration" of certain embodiments, the count pawl happened to be engaged with the ratchet wheel, that was an inessential aspect of the invention as a whole. *See, e.g.*, '156 Patent, 5:39-65, 11:39-44, 11:48-49, 14:11-15:33, 17:24-61, Figs. 9, 10A-10F, 11, 14.

286. In my opinion, to the extent that Cipla's ANDA Product does not literally satisfy this limitation under Defendants' proposed constructions, the differences between Cipla's start configuration and the claimed start configuration are insubstantial. In both cases, the actuator pawl is spaced from a first tooth of the ratchet wheel. *See, e.g.*, Cipla Samples; CIPLA-

BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 (Design Drawings); CIPLA-BDI_0803837-38 (Design Drawings). To the extent that there are differences in the position of the count pawl, those differences are not essential to the invention. *See, e.g.*, '156 Patent, 5:39-65, 11:39-44, 11:48-49, 14:11-15:33, 17:24-61, Figs. 9, 10A-10F, 11, 14.

287. Alternatively, Cipla's start configuration and the claimed start configuration perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of facilitating describing the actuator pawl at certain times, by way of defining reference points, to obtain the result of facilitating designing and manufacturing dose counters with appropriate tolerances. *See, e.g.*, '156 Patent, 5:39-65, 11:39-44, 11:48-49, 14:11-15:33, 17:24-61, Figs. 9, 10A-10F, 11, 14.

288. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation (including under Defendants' proposed constructions). For example, physical inspection confirms that (1) Cipla's dose counter is arranged to define a start position, in which the actuator pawl is spaced from the ratchet wheel; (2) Cipla's dose counter is arranged to define a first reset position, in which Cipla's actuator pawl is brought into engagement with a first tooth of the ratchet wheel; and (3) Cipla's actuator pawl is closer to a datum plane passing through a shoulder of the valve stem block when Cipla's dose counter is in the start configuration than when it is in the first reset position. *See, e.g.*, Cipla Samples.

289. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise an "actuator pawl" or "actuator." *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 1. I disagree for the reasons stated in connection with those limitations. *See, e.g.*, *supra* Section VIII.C.1.d.2) ('156 Patent, Claim 1).

f. "Wherein the Actuator Is Further Arranged Such That, During a Canister Fire Sequence, When the Actuator Is in a Second Position, Which Is After the First Reset Position and at a Canister Fire Configuration, the Medicament Canister Fires Medicament Before the Dose Counter Reaches a Count Configuration, and When the Actuator Is in a Third Position After the Second Position, the Count Pawl Resiliently Jumps Over the Second Tooth and the Dose Counter Reaches the Count Configuration, Whereby the Dosage Indicator Has Indicated a Count"

290. In my opinion, Cipla's ANDA Product comprises a dose counter "wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count."

291. I have been informed that the parties have proposed different constructions of the terms "canister fire sequence," "first reset position," "canister fire configuration," and "count configuration." I reproduce the parties' proposed constructions below.

Claim Term	Teva's Construction	Defendants' Construction
"canister fire sequence"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"	"process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to

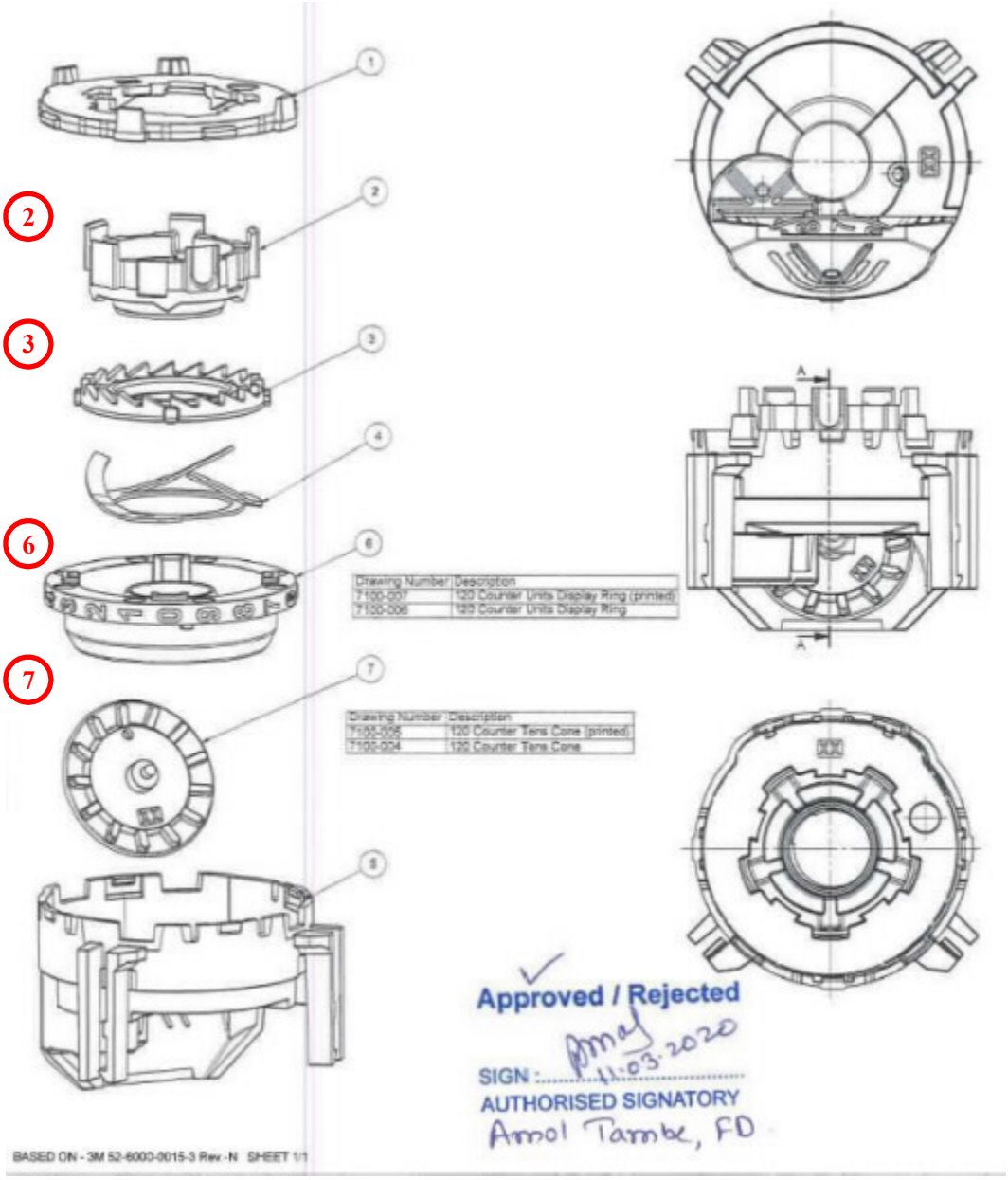
		depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel."
"first reset position"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration"	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"
"canister fire configuration"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter in which the medicament canister fires medicament"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"
"count configuration"	Plain and ordinary meaning in view of the claims, specification, and prosecution history. "a configuration of the dose counter whereby the dosage indicator has indicated a count"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"

I have also been informed that Defendants have further proposed that the term "start configuration," which does not appear in claim 1, should be construed to mean "in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel." I have not been asked to

provide an opinion about which constructions are correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under any of the proposed constructions.

292. **Teva's Proposed Constructions.** Cipla's ANDA Product literally satisfies this limitation under Teva's proposed constructions.

293. As discussed above, Cipla's dose counter comprises (what Cipla refers to as) an "indexer" (2), "units teeth ring" (3), "units display ring" (6), and "tens cone" (7).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

294. Cipla's dose counter is further arranged to define a canister fire sequence, consisting of a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament.

295. First Reset Position: When a patient presses down on Cipla's medicament canister, Cipla's medicament canister moves downward through the space between Cipla's medicament canister and Cipla's actuator (i.e., what Cipla refers to as an "indexer"). Cipla's medicament canister presses down on Cipla's indexer, which causes Cipla's actuator pawl to (i.e., one or more of the triangular protrusions on the bottom of Cipla's indexer) to engage with one or more of the inner teeth of Cipla's ratchet wheel (i.e., what Cipla refers to as a "units teeth ring").

296. Canister Fire Configuration: As Cipla's actuator pawl presses down on one or more of the inner teeth of Cipla's ratchet wheel, that pressure causes Cipla's ratchet wheel to rotate, causing it to rotate. As Cipla's ratchet wheel rotates, another of the inner teeth of Cipla's ratchet wheel engages with Cipla's count pawl (i.e., another of the triangular protrusions on the bottom of what Cipla refers to as an "indexer"). The rotation of Cipla's ratchet wheel further causes Cipla's dosage indicator (i.e., one or more of what Cipla's refers to as a "units display ring" and "tens cone") to start rotating. While Cipla's units display ring and/or tens cone are rotating, but before they have stopped doing so, Cipla's medicament canister fires medicament.

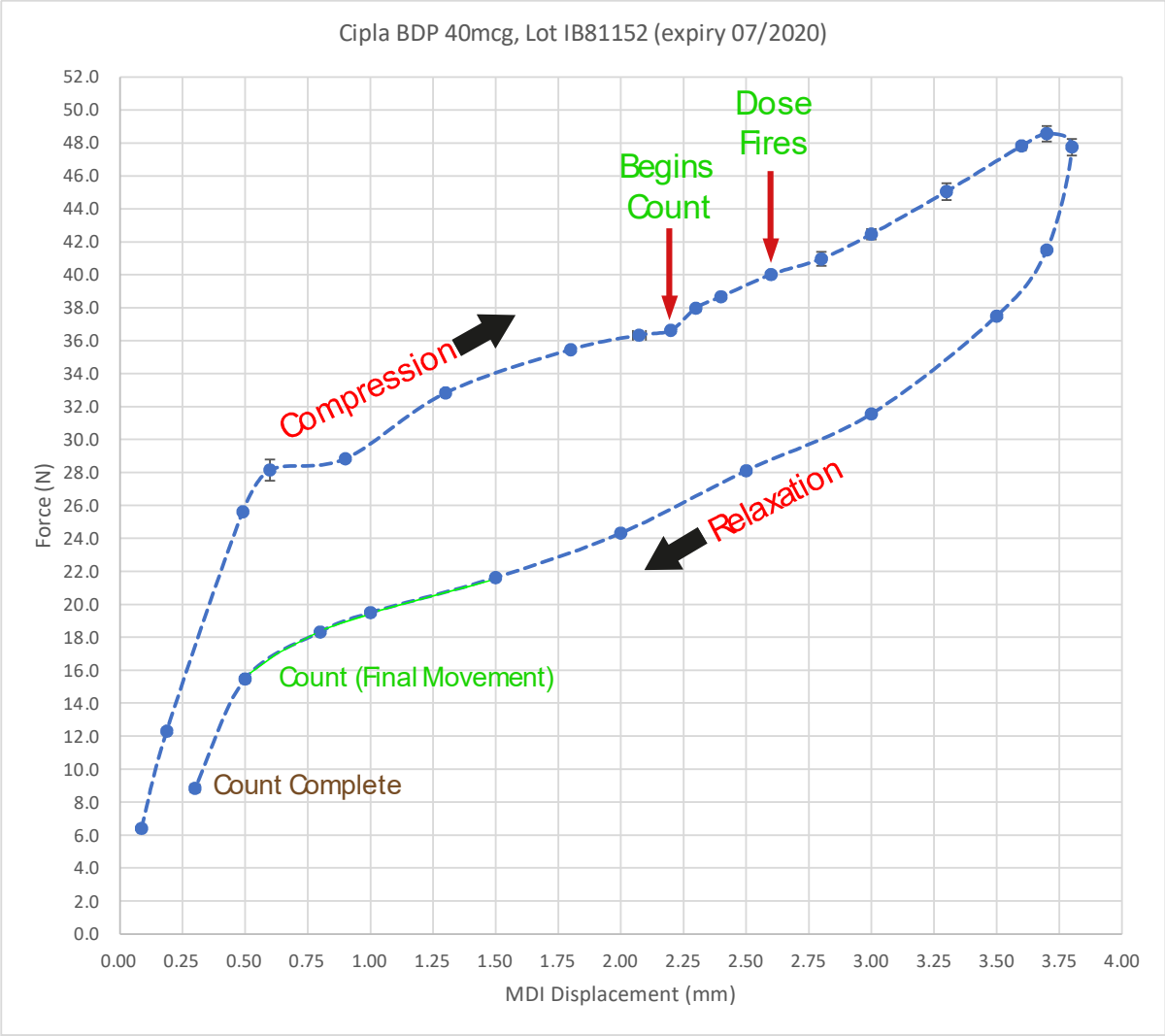
297. Count Configuration: After Cipla's medicament canister fires, Cipla's dosage indicator stops rotating, at which point Cipla's dosage indicator has registered a count. By the

time Cipla's dosage indicator registers a count, Cipla's count pawl has disengaged with (i.e., resiliently jumped over) the tooth of the ratchet wheel with which it was engaged.

298. Exhibit C describes experiments measuring the amount of force and distance needed to cause Cipla's ANDA Product to fire and count. Below, I reproduce two force-displacement curves resulting from that experiment.

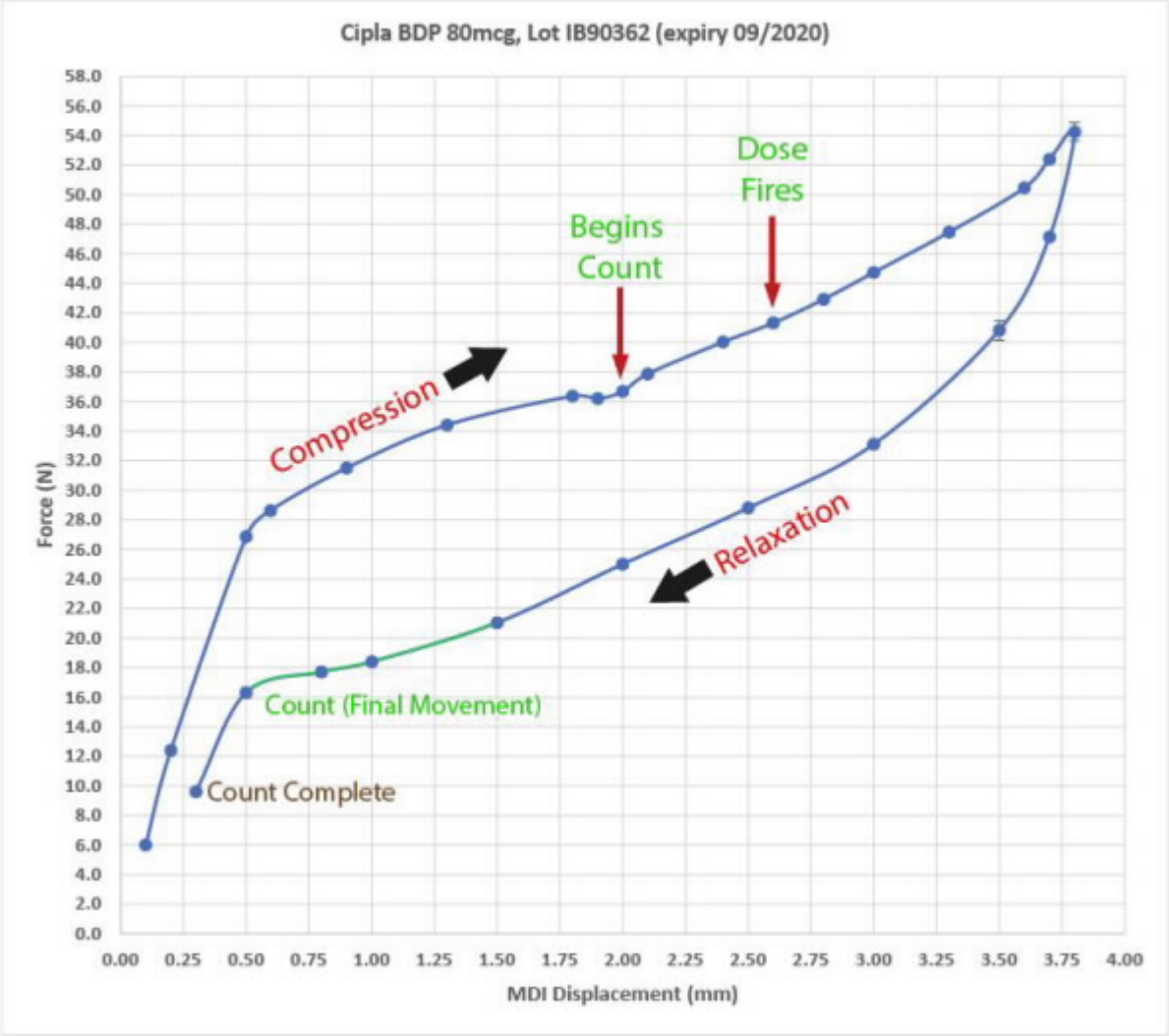
Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Replicates, n = 5



Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Replicates, n = 5



As the above curve illustrates, Cipla's dose counter undergoes the following sequence: (1) Cipla's medicament comes into contact with Cipla's actuator, which causes Cipla's actuator pawl to press down on a first inner tooth of Cipla's units teeth ring; (2) Cipla's dosage indicator starts rotating (i.e., "begins count"); (3) Cipla's medicament canister fires; and (4) Cipla's dosage indicator stops rotating (i.e., "count complete"). Thus, Cipla's dose counter passes through the first reset position, canister fire configuration, and count configuration in that order.

299. **Defendants' Proposed Constructions:** In my opinion, Cipla's ANDA Product

also satisfies this limitation under Defendants' proposed constructions, at a minimum, under the doctrine of equivalents.

300. Defendants' proposed constructions are similar to Teva's, except that (1) Defendants' proposed construction of "canister fire sequence" requires Cipla's ANDA dose counter to be arranged to define a start configuration, prior to depression of the canister, in which the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel; and (2) Defendants' proposed constructions of "first reset position," "canister fire configuration," and "count configuration" require Cipla's actuator pawl to be in certain vertical positions relative to each other and/or a datum plane passing through a shoulder of Cipla's valve stem block.

301. As explained above in connection with the previous limitation, at a minimum, Cipla's ANDA Product satisfies Defendants' requirement that Cipla's ANDA Product be arranged to define a start configuration under the doctrine of equivalents. *See, e.g.*, *supra* Section VIII.C.1.e ('156 Claim 1).

302. With respect to the remaining requirements, the force-displacement curve presented in connection with Teva's proposed constructions shows, at a minimum, that (1) when Cipla's dose counter is in the "first reset position," (i.e., when Cipla's actuator pawl is just engaged with one of a tooth of the ratchet wheel), Cipla's actuator pawl is above the datum plane, but closer to the datum plane than in the start configurations; (2) when Cipla's dose counter is in the "canister fire configuration" (i.e., when the medicament is ejected), Cipla's actuator pawl is lower than in the first reset position and below the datum plane. Thus, at a minimum, Cipla's ANDA Product literally satisfies those requirements under Defendants' proposed constructions.

303. I discuss the position of Cipla's actuator pawl during the "start configuration," "first reset position," "canister fire configuration," and "count configuration" in connection with the limitation below, in greater detail. *See, e.g.*, *infra* Section VIII.A.1.g ('156 Patent, Claim 1).

304. In my opinion, to the extent that Cipla's ANDA Product does not satisfy the Defendants' proposed constructions of the "start configuration," "first reset position," "canister fire configuration," or "count configuration"—for example, Defendants' requirement that in the "count configuration" (i.e., when Cipla's dose counter has counted one dose), Cipla's actuator pawl is further below the datum plane than when in the canister fire position— Cipla's ANDA Product satisfies these requirements under the doctrine of equivalents.

305. As discussed in connection with the limitation above, the '156 Patent uses the terms "canister fire sequence," "start configuration," "first reset position," "canister fire configuration," and "count configuration" as reference points, for describing the actuator pawl at certain times during the operation of various embodiments. The '156 Patent further describes that the purpose of defining these reference points is to facilitate designing and manufacturing dose counters with appropriate tolerances, to avoid under- or over-counting. *See, e.g.*, '156 Patent, 5:39-65, 11:39-44, 11:48-49, 14:11-15:33, 17:24-61 ("FIG. 14 shows a computer system 230 for designing the dose counter 36 and in particular for calculating distributions representative of average positions and standard deviations in a production series of inhalers of the start, reset, fire, count and end positions of the actuator lower side edge 98 relative to the datum plane 220 (FIG. 9) . . ."); *id.* Figs. 9, 10A-10F, 11, 14; *supra* Section VIII.A.1.e ('156 Patent, Claim 1).

306. From this, the POSA would understand that what was essential about the terms "canister fire sequence," "start configuration," "first reset position," "canister fire configuration,"

and "count configuration" was that they described a temporal sequence of events. The POSA would understand that, although, in certain embodiments, those reference points are framed in terms of the actuator pawl's relative position (i.e., travel distance relative to a particular design feature), they could be framed in terms of the actuator pawl's absolution position (i.e., total travel distance) without undermining an essential aspect of the inventions.

307. Thus, in my opinion, any differences between Cipla's canister fire sequence, start configuration, first reset position, canister fire configuration, and count configuration and the claimed ones are insubstantial. As in the claimed inventions, Cipla's dose counter is arranged such that it undergoes the following sequence (1) the patient presses down on the medicament canister; (2) the actuator pawl engages a first tooth of the ratchet wheel; (3) the medicament canister fires medicament; and (4) the dosage indicator counts. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings). Whether they framed in terms of the actuator pawl's relative or absolute position is inessential.

308. Alternatively, in my opinion, Cipla's canister fire sequence, start configuration, first reset position, canister fire configuration, and count configuration and the claimed ones perform substantially the same function in substantially the same way to obtain the same result. All perform the function of facilitating describing the actuator pawl at certain times, by way of defining reference points, to obtain the result of facilitating designing and manufacturing dose counters with appropriate tolerances. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

309. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA

Product satisfies this limitation. For example, physical inspection confirms that (1) Cipla's dose counter is arranged to define a canister fire sequence, consisting of a start position, first reset position, canister fire configuration, and count configuration in that order; (2) in the start position, Cipla's actuator pawl is spaced from the ratchet wheel; (3) in the first reset position, when Cipla's actuator pawl is brought into engagement with a first tooth of the ratchet wheel, Cipla's actuator pawl is above a datum plane passing through a shoulder of the valve stem block, but closer to the datum plane than in the start configuration; and (4) in the canister fire sequence, when Cipla's medicament canister fires, Cipla's actuator pawl is below a shoulder of the valve stem block. *See, e.g.*, Cipla Samples.

310. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise an "actuator pawl," "actuator," or "count pawl." *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 1. I disagree for the reasons stated in connection with those limitations. *See, e.g.*, *supra* Sections VIII.C.1.d.2)-VIII.C.1.d.3) ('156 Patent, Claim 1).

g. "Wherein, in the Canister Fire Configuration, the Actuator Pawl Is Below a Datum Plane Which Passes Through a Shoulder of a Valve Stem Block Configured to Receive the Medicament Canister"

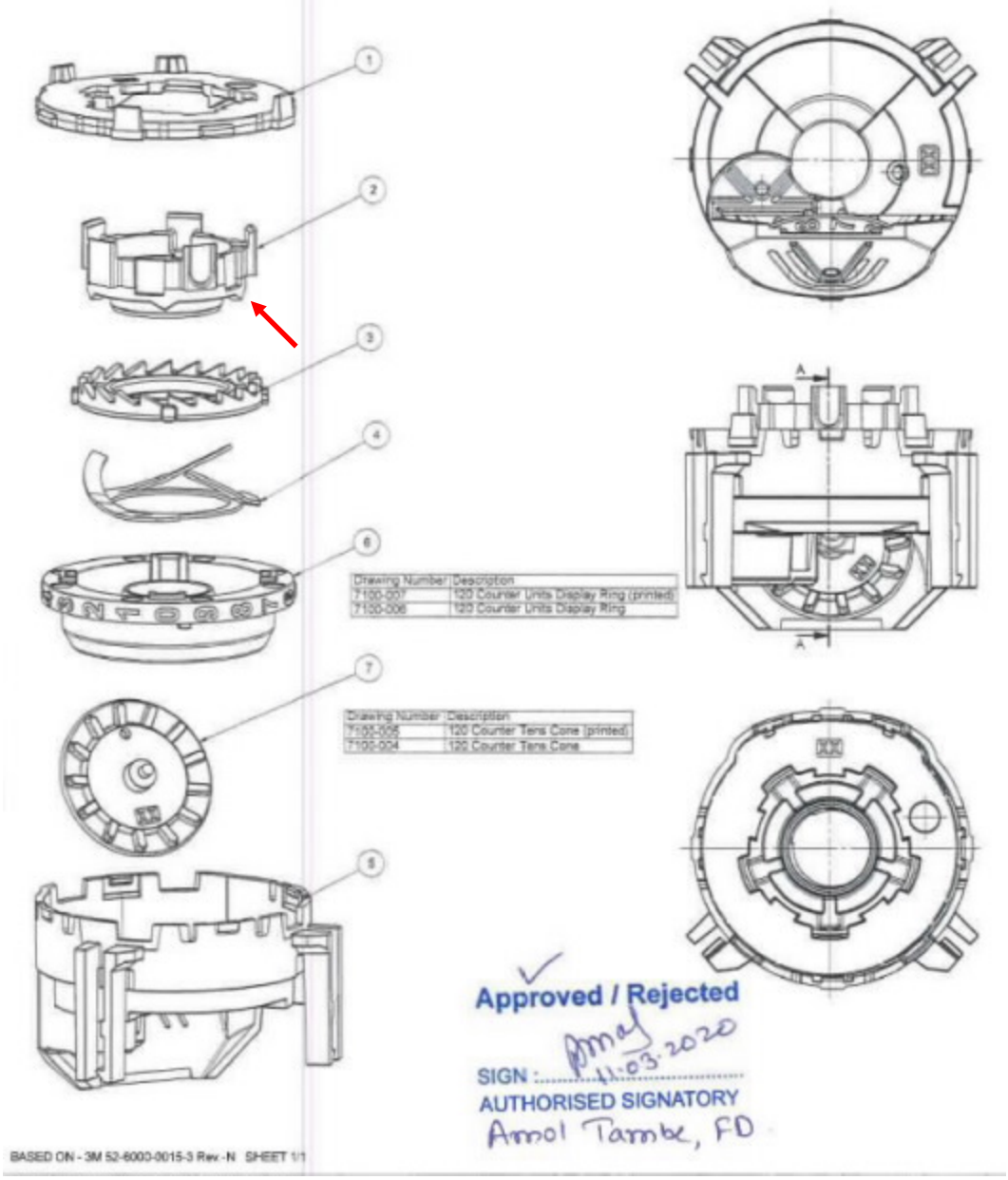
311. In my opinion, Cipla's ANDA Product comprises a dose counter "wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister."

312. I have been informed that the parties have proposed different constructions for the terms "canister fire configuration" and "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." I have been informed that Teva has proposed that the terms should be construed in accordance with their plain and ordinary

meanings in view of the claims, specification, and prosecution history, to mean "a configuration of the dose counter in which the medicament canister fires medicament" and "a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister," respectively. I have been informed that Defendants propose that the terms should be construed to mean a "configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected" and a "plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet". I have not been asked to provide an opinion about which constructions are correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under any proposed constructions.

313. **Teva's Proposed Constructions.** In my opinion, Cipla's ANDA Product literally satisfies this limitation under Teva's proposed constructions.

314. As explained above, Cipla's dose counter comprises an actuator pawl (i.e., one or more of the triangular protrusions on what Cipla refers to as an "indexer") (arrow). *See, e.g.*, *supra* Section VIII.C.1.d.2) ('156 Patent, Claim 1).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

315. As depicted below, Cipla's ANDA Product further comprises a valve stem block (red arrow), which is the portion of the inhaler body that engages with (i.e., inserts into) the valve stem of Cipla's medicament canister. Cipla's valve stem block is shaped such that it has it

has at least one shoulder-like portion (green arrow).

316. When a patient presses down on Cipla's medicament canister, Cipla's dose counter passes through a canister fire sequence, consisting of a first reset position, canister fire configuration (i.e., when Cipla's medicament canister fires), and count configuration (i.e., when Cipla's dose counter counts). *See, e.g.*, *supra* Sections VIII.C.1.e-VIII.C.1.f ('156 Patent, Claim 1). Because Cipla's medicament canister moves perpendicularly with respect to Cipla's valve stem block, it is possible to construct a datum plane (blue arrow) that passes through the shoulder of that valve stem block and is perpendicular to the movement of Cipla's medicament canister.

See, e.g., CIPLA-BDI_0803837-38 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579 (Design

Drawings).

317. Under Teva's proposed constructions, whether Cipla's ANDA Product satisfies this limitation therefore depends on whether, when Cipla's dose counter reaches the canister fire configuration (i.e., when Cipla's medicament canister fires), Cipla's actuator pawl (i.e., one or more of the triangular protrusions on the bottom of what Cipla refers to as an "indexer") is beneath that datum plane. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

318. Exhibit C describes experiments measuring the amount of force and distance needed to cause Cipla's ANDA Product to fire and count. To determine whether Cipla's ANDA Product satisfies these limitations, I measured (1) the distance between the top of Cipla's "indexer" and the actuator pawl; (2) the distance that the top of Cipla's "indexer" has moved (i.e., its displacement) when Cipla's medicament canister fires; and (3) the distance between the top of Cipla's "indexer" and the datum plane passing through the shoulder of the valve stem block identified above.

319. I found that (1) the distance between the top of Cipla's "indexer" and the actuator pawl is 5.64 ± 0.02 mm and 5.61 ± 0.02 mm for Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020), and Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020), respectively. I further found that (2) when Cipla's ANDA Product fires, Cipla's "indexer" has moved 2.600 mm. I found that (3) the distance between Cipla's "indexer" and the datum plane passing through the shoulder of the valve stem block is -5.48 ± 0.03 and -5.45 ± 0.12 mm for Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020), and Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020), respectively. These results entail that, when Cipla's ANDA Product

fires, Cipla's actuator pawl is beneath a shoulder of the valve stem block. Thus, in my opinion, Cipla's ANDA Product satisfies this limitation under Teva's proposed constructions.

320. [redacted]

321. **Defendants' Proposed Constructions.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed construction, at a minimum, under the doctrine of equivalents.

322. Under Defendants' proposed constructions Cipla's actuator pawls must be the "plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet" (which I have been informed that Defendants contend to be one of the lowest two of the three datum planes illustrated above). In my opinion, to the extent that Cipla's ANDA Product does not satisfy this limitation literally, it does so under the doctrine of equivalents.

323. The '156 Patent confirms this analysis. As illustrated in, for example, Figure 9, the '156 Patent describes the datum plane as a reference point for measuring the height of the actuator pawl in the first reset position, canister fire configuration, and count configuration. '156 Patent, 13:42-15:33; 17:24-61 Figs. 9, 10A-10F, 11, 14.

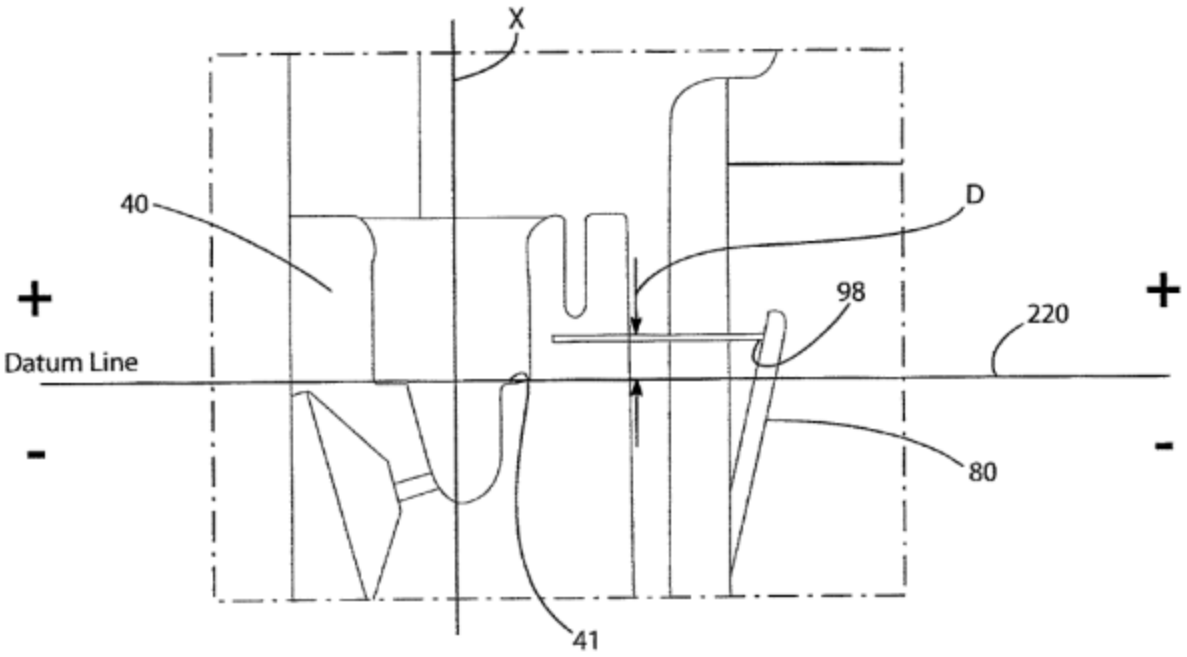


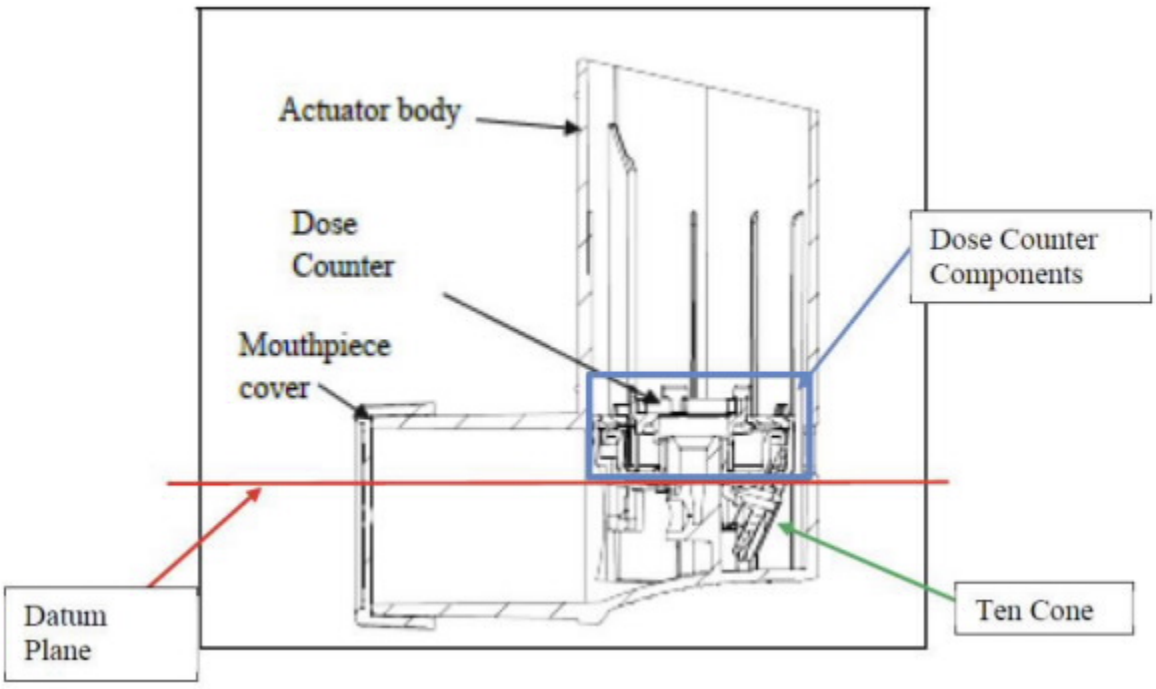
FIG. 9

'156 Patent, Fig. 9. Although, in certain embodiments, the datum plane passes through a shoulder that I have been informed Defendants contend to be the "bottom surface" of the valve stem block, the POSA would understand that a datum plane passing through any shoulder-like portion of the valve stem block that was perpendicular to the movement of the medicament canister could satisfy this purpose.

324. Accordingly, in my opinion, to the extent that Cipla's ANDA Product does not literally satisfy this limitation, the differences between the shoulder-like portion of Cipla's valve stem block described above and the one that Defendants contend to be the "shoulder" are insubstantial. Both are shoulder-like surfaces that are horizontal to the movement of the medicament canister, which can be used to determine the relative position of Cipla's actuator pawl during the canister fire sequence. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

325. Alternatively, in my opinion, both perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of providing a horizontal reference point, by way of providing a horizontal surface, to obtain the result of permitting the POSA to determine the relative position of Cipla's actuator pawl during the canister fire sequence. *See* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

326. Cipla contends that it does not infringe this limitation because, purportedly, "any structure Plaintiffs could allege corresponds to an 'actuator pawl' is above the datum plane in all configurations. *See* [CIPLABDI_0156595; CIPLA-BDI_0156597; CIPLA_P_000001-50; CIPLA-BDI_0156579; and CIPLA-BDI_0004411-705]; *see* figure below." Cipla Non-Infringement Contentions,'156 Patent, Claim 1. Cipla further provides the following diagram.



Cipla Non-Infringement Contentions,'156 Patent, Claim 1. I have reviewed the materials Cipla cites and, for the reasons stated above, I disagree. At a minimum, Cipla's ANDA Product

satisfies this limitation under the doctrine of equivalents.

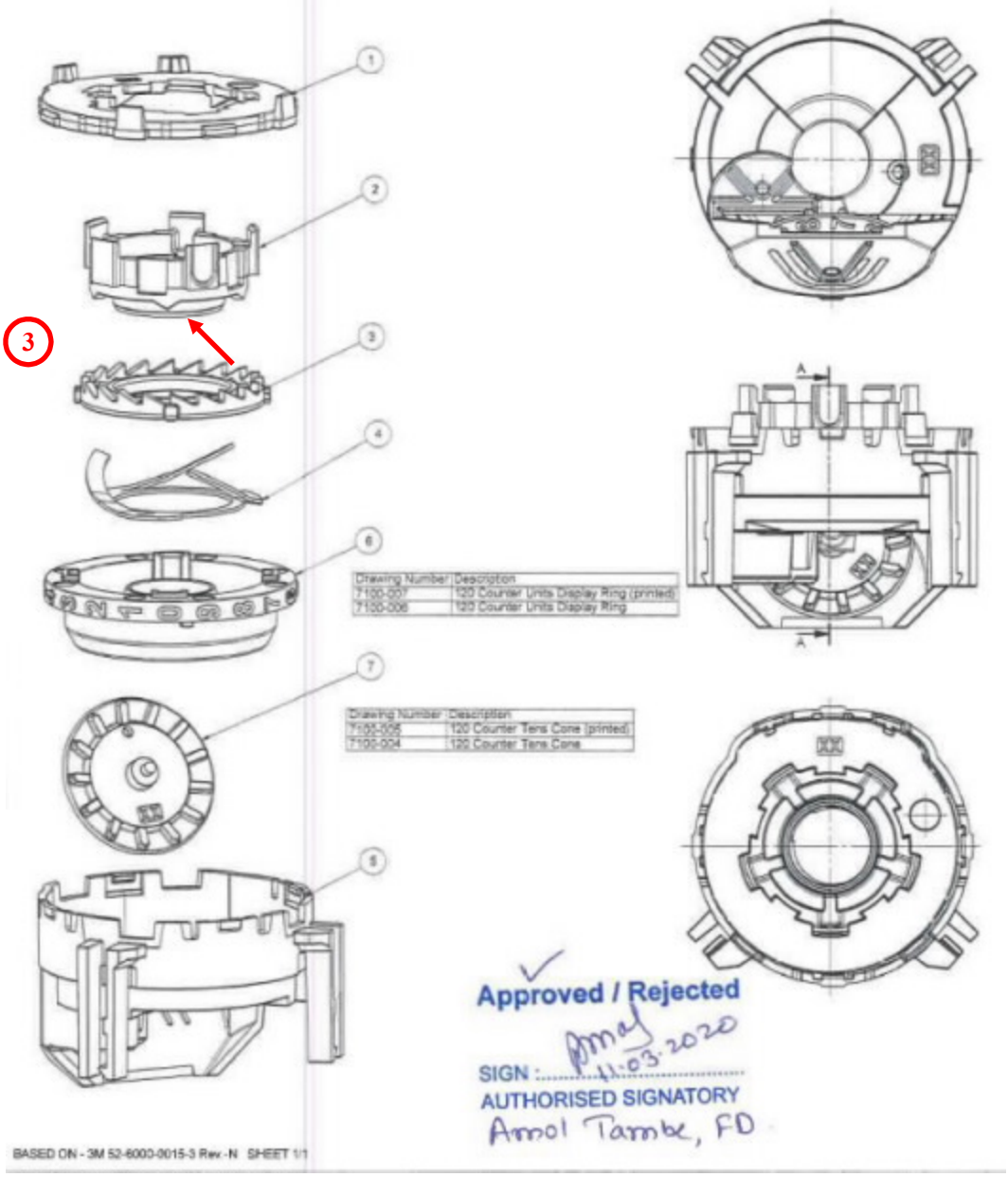
327. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation, for example, because it confirms that Cipla's actuator pawl is beneath at least one shoulder of Cipla's valve stem block during the canister fire configuration. *See, e.g.*, Cipla Samples.

328. Cipla also contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise an "actuator pawl." *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 1. I disagree for the reasons stated in connection with that limitation. *See, e.g.*, *supra* Section VIII.C.1.d.2) ('156 Patent, Claim 1).

2. '156 Patent, Claim 9

329. Claim 9 of the '156 Patent recites: "A dose counter as claimed in claim 1, wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

330. Cipla's ANDA Product satisfies the limitations of claim 1, as explained above. *See, e.g.*, *supra* Section VIII.C.1 ('156 Patent, Claim 1). In my opinion, Cipla's ANDA Product further satisfies the limitation "wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion therebetween." As explained above, Cipla's dose counter comprises a count pawl (i.e., one or more of the triangular protrusions on the bottom of what Cipla refers to as an "indexer") (arrow) and a ratchet wheel (i.e., what Cipla refers to as a "units teeth ring") (3). *See, e.g.*, *supra* Sections VIII.C.1.d.1)-VIII.C.1.d.3) ('156 Patent, Claim 1).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

331. As illustrated above, Cipla's count pawl and ratchet wheel are shaped such that when used, Cipla's dose counter moves incrementally in one direction (i.e., Cipla's dose counter counts downward, but not upward). This is evidenced, for example, by the triangular shapes of

the teeth of Cipla's ratchet wheel and Cipla's count pawl (i.e., one or more of the triangular protrusions on what Cipla refers to as an "indexer"), which permit Cipla's dose counter to count forward, but resist movement in the opposite direction. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579 CIPLA-BDI_0803837-38 (Design Drawings).

332. [redacted]

333. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that Cipla's count pawl and actuator pawl shaped such that, when used, Cipla's dose counter counts downward, but not upward. *See, e.g.*, Cipla Samples.

334. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '156 Patent. *See* Cipla Non-Infringement Contentions,'156 Patent, Claim 9. I disagree for the reasons stated in connection with that claim. *See, e.g.*, *supra* Section VIII.C.1 ('156 Patent, Claim 1).

3. '156 Patent, Claim 11

335. Claim 11 of the '156 Patent recites: "An inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed

in claim 1." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

336. Cipla's ANDA Product comprises a dose counter that meets the limitations of claim 1, as explained above. *See, e.g.*, *supra* Section VIII.C.1 ('156 Patent, Claim 1). In my opinion, Cipla's ANDA Product further comprises an "inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1." Cipla's ANDA Product is an inhaler. *See, e.g.*, *supra* Section VIII.A.1.a ('289 Patent, Claim 1). And Cipla's inhaler body is further "arranged to retain the medicament canister of predetermined configuration." *See, e.g.*, *supra* Section VIII.C.1.b ('156 Patent, Claim 1).

337. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this claim. *See, e.g.,* Cipla Samples.

338. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claim 1 of the '156 Patent. *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 11. I disagree for the reasons stated above in connection with that claim. *See, e.g.*, *supra* Section VIII.C.1 ('156 Patent, Claim 1).

4. '156 Patent, Claim 12

339. Claim 12 of the '156 Patent recites: "An inhaler as claimed in claim 11 in which the body includes a canister-receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator."

340. I have been informed that the parties have proposed different constructions for the term "separate counter chamber." I have been informed that Teva proposes that the term should

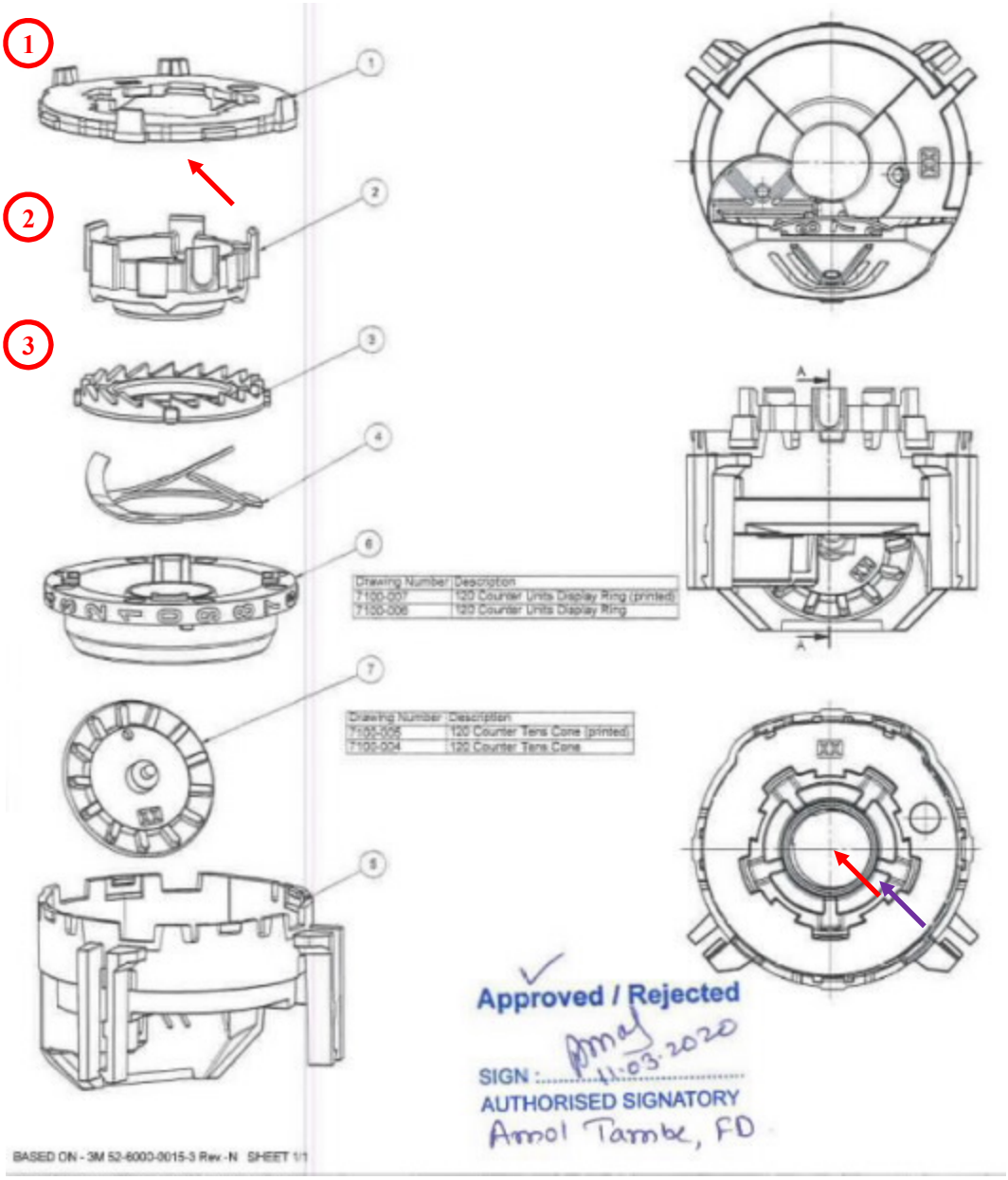
be construed according to its plain and ordinary meaning in view of the claims, specification, and prosecution history, to mean "a separate chamber of the inhaler in which the dose counter is located." I have been informed that Defendants propose that the term should be construed to mean a "discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

341. Additionally, I have been informed that the parties have proposed different constructions for the term "body," as it appears in this claim. I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning in view of the claims, specification, and prosecution history, to mean the "inhaler body" at 22:64, 67; and the "dose counter body" at 22:66. I have been informed that Defendants contend that the term is indefinite, an issue on which they bear the burden of proof by clear and convincing evidence. As of this report, I have not been asked to provide an opinion about which position is correct, and I express no opinion on that issue.

342. In my opinion, Cipla's ANDA Product is an inhaler that satisfies the limitations of claim 11, as explained above. In my opinion, Cipla's ANDA Product further satisfies the limitations of claim 12, assuming the term "body" is definite.

343. **Teva's Proposed Construction.** In my opinion, Cipla's ANDA Product literally satisfies these limitations under Teva's proposed construction of "separate counter chamber." As explained above, Cipla's ANDA Product comprises an inhaler body that includes a counter receiving portion and a dose counter. *See, e.g.*, *supra* Sections VIII.A.1.b-VIII.A.1.d ('289

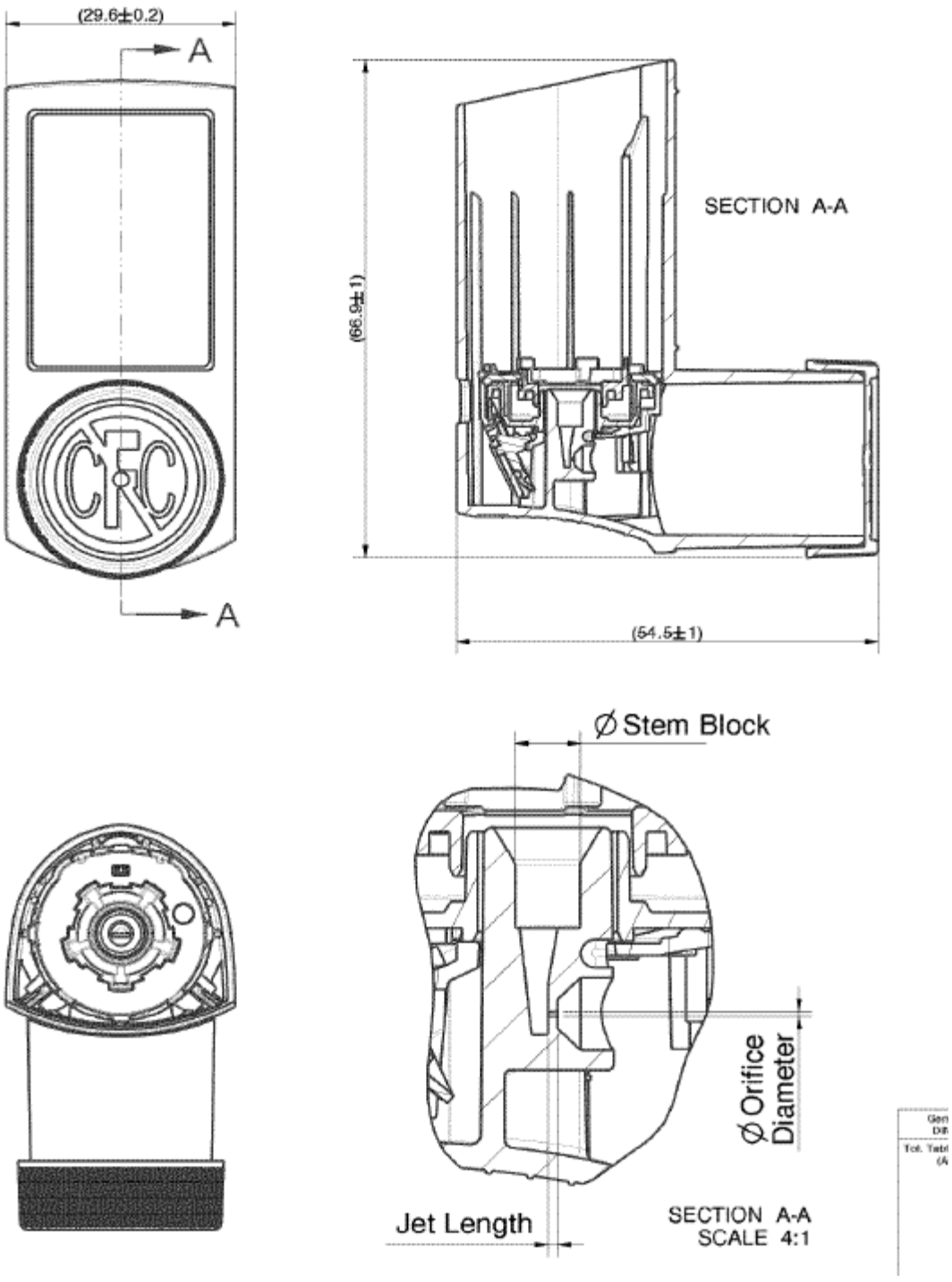
Patent, Claim 1). Cipla's dose counter further comprises a ratchet wheel (3), actuator (2), and (what Cipla refers to as) a "lid" (1). *See, e.g.*, *supra* Sections VIII.A.3, VIII.C.1.d.1)-VIII.C.1.d.2) ('289 Patent, Claim 1; '156 Patent, Claim 1). Cipla's lid has a communication aperture on its top (arrows), through which Cipla's actuator extends. *See, e.g.*, *supra* Section VIII.A.3 ('289 Patent, Claim 3).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-

BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

344. As depicted below, when Cipla's ANDA Product is assembled, Cipla's dose counter—including its dose counter body, ratchet wheel, and actuator—is located in a separate chamber of the inhaler body, which is separated from the canister-receiving portion of the inhaler body by the inner wall surfaces and the lid.



See, e.g., CIPLA-BDI_0803837-38 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579 (Design Drawings).

345. Cipla contends that it does not infringe this claim because, purportedly, Cipla's ANDA Product "does not have a body that includes 'a separate counter chamber.' *See* CIPLA-BDI_0156595; CIPLA-BDI_0156597; CIPLA_P_000001-50; CIPLA- BDI_0156579; and CIPLA-BDI_0004411-705." Cipla Non-Infringement Contentions, '156 Patent, Claim 12. Cipla further contends that Cipla's ANDA Product does not comprise the relevant "wall surfaces" and "communication aperture." I have reviewed the materials Cipla cites, and I disagree. As I explain above, Cipla's ANDA Product satisfies each of those limitations.

346. Additionally, in my opinion, to the extent that Cipla's ANDA Product does not literally comprise a separate counter chamber, it does so under the doctrine of equivalents.

347. The '156 Patent describes that, in certain embodiments, the inhaler body comprises a separate chamber. In those embodiments, the counter chamber provides a space in the inhaler body where the dose counter is located, which is separate from the canister-receiving portion of the inhaler body. Thus, the inner wall surfaces of the inhaler body separate the canister-receiving portion of the inhaler body from the sensitive elements of the dose counter, including the ratchet wheel and counter display. *See, e.g.*, '156 Patent 6:20-33, 6:34-7:25, 8:28-53, 12:15-55, 13:12-54, 16:10-17:23, Figs. 4A, 6H, 8A-8D.

348. Accordingly, to the extent that Cipla's ANDA Product does not literally comprise a separate counter chamber, the differences between the space created by Cipla's inner wall surfaces and lid and the claimed separate counter chamber are insubstantial. Both are spaces that separate the canister-receiving portion of the inhaler body from the sensitive elements of the dose counter, including the ratchet wheel and inhaler body. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

349. Alternatively, the space created by Cipla's inner wall surfaces and lid and the claimed separate counter chamber perform substantially the same function in substantially the same way to obtain the same result. Both perform the function of separating the canister-receiving portion of the inhaler body from the sensitive elements of the dose counter, including the ratchet wheel and inhaler body, by way of creating a separate space within the inhaler body, to obtain the result of protecting the sensitive elements of the dose counter. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

350. [redacted]

351. [redacted]

[redacted]

352. **Defendants' Proposed Construction.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed construction, both literally and under the doctrine of equivalents.

353. Defendants' proposed construction requires the "separate counter chamber" to be a "discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located." As explained in connection with Teva's proposed construction, Cipla's inner walls and the lid through which a portion of the actuation member (i.e., one or more of the triangular protrusions on the bottom of what Cipla's refers to as an "indexer") define a discrete space or cavity in which the dose counter is located. As further explained in connection with Teva's proposed construction, to the extent that Cipla's ANDA Product does not literally satisfy that limitation, it does so under the doctrine of equivalents.

354. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA

Product satisfies this claim, including because it confirms that (1) Cipla's inhaler body includes a canister-receiving portion and a separate counter chamber; (2) Cipla's dose counter has a body, ratchet wheel, and actuator that are located inside the counter chamber; (3) Cipla's inhaler body has inner wall surfaces and a lid separating the canister-receiving portion and the counter chamber; (4) Cipla's lid has a communication aperture; and (5) Cipla's actuation member extends through the communication aperture to transmit canister motion to the actuator. *See, e.g.*, Cipla Samples.

355. Cipla also contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1 and 11 of the '156 Patent. *See* Cipla Non-Infringement Contentions,'156 Patent, Claim 12. I disagree for the reasons stated in connection with those claims. *See, e.g.*, *supra* Sections VIII.C.1, VIII.C.3 ('156 Patent, Claims 1, 11).

5. '156 Patent, Claim 13

356. Claim 13 of the '156 Patent recites: "The dose counter of claim 1, wherein the shoulder is a bottom surface within the value stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

357. Cipla's ANDA Product comprises a dose counter of claim 1, as explained above. *See, e.g.*, *supra* Section VIII.C.1 ('156 Patent, Claim 1). The remaining requirements of claim 13 mirror Defendants' proposed construction of the term "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." For the reasons explained in connection with that claim, Cipla's ANDA Product satisfies that limitation under Defendants' proposed construction, at a minimum, under the doctrine of equivalents. *See, e.g.*, *supra* Section VIII.C.1.g ('156 Patent, Claim 1).

358. Cipla contends that it does not infringe this claim for the same reasons that it does

not infringe claim 1 of the '156 Patent. *See* Cipla Non-Infringement Contentions, '156 Patent, Claim 13. I disagree for the reasons stated above in connection with that claim. *See, e.g.*, *supra* Section VIII.C.1 ('156 Patent, Claim 1).

D. U.S. Patent No. 10,561,808 ('808 Patent)

1. '808 Patent, Claim 1

359. In my opinion, Cipla's ANDA Product satisfies every limitation of claim 1 of the '808 Patent.

360. Claim 1 recites as follows:

> 1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movement.

I address each limitation of this claim below.

a. "A Dose Counter for an Inhaler"

361. In my opinion, Cipla's ANDA Product comprises a "dose counter for an inhaler." *See, e.g.*, *supra* Sections VIII.A.1.a, VIII.A.1.d ('289 Patent, Claim 1). Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. *See, e.g.*, Cipla Samples. Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions,'808 Patent, Claim 1.

b. "The Dose Counter Having"

1) "A Counter Display Arranged to Indicate Dosage Information"

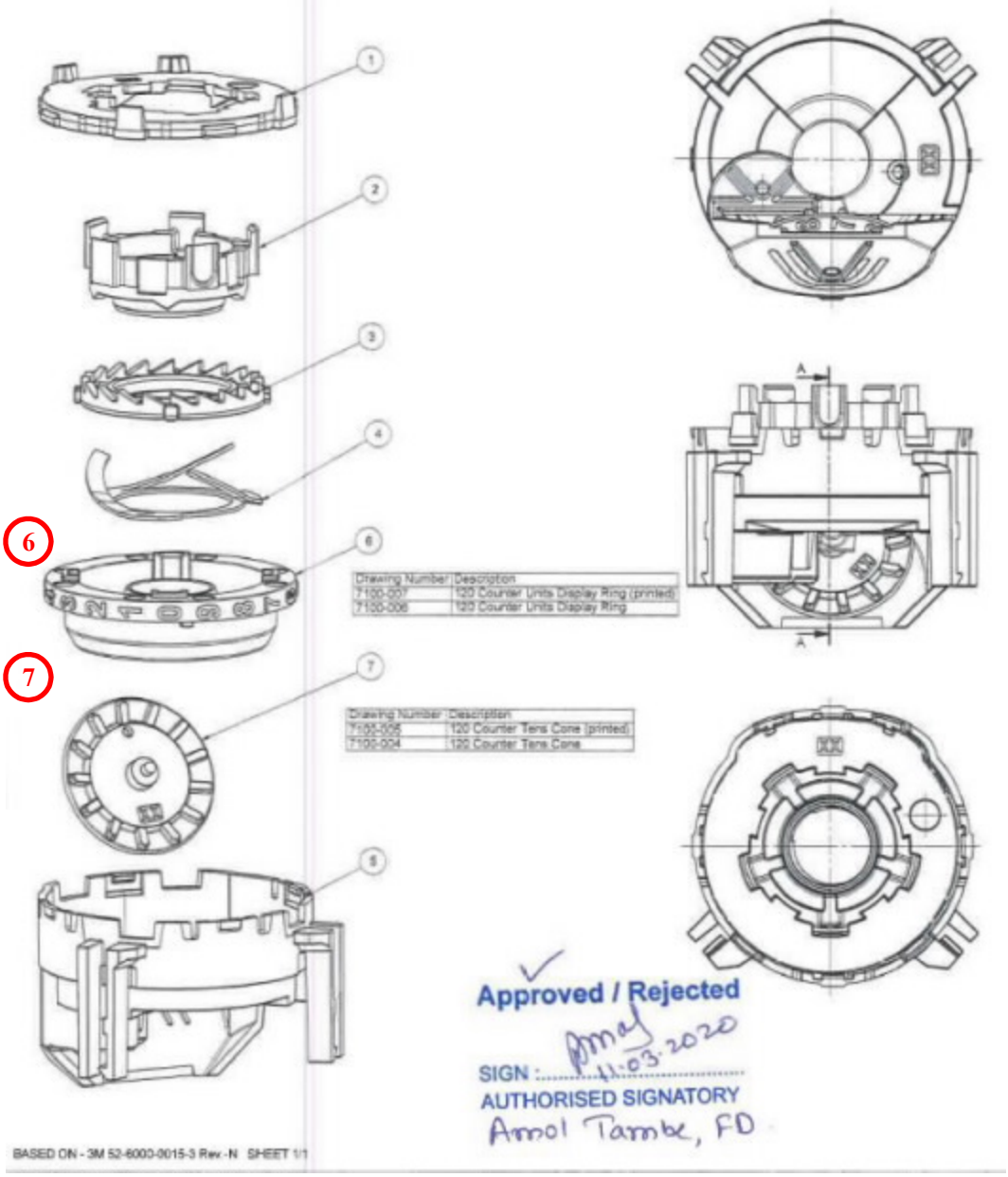
362. In my opinion, Cipla's ANDA Product comprises a "dose counter having a counter display arranged to indicate dosage information."

363. I have been informed that the parties have proposed different constructions for the

term "counter display arranged to indicate dosage information." I have been informed that Teva proposes that the term should be construed according to its plain and ordinary meaning, in view of the claims, specification, and prosecution history, to mean "a component of the dose counter that displays information regarding the number of doses remaining." I have been informed that Defendants propose that the term should be construed to mean "structure displaying the number of doses remaining." I have not been asked to provide an opinion about which construction is correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under either proposed construction.

364. **Teva's Proposed Construction.** In my opinion Cipla's ANDA Product literally satisfies this limitation under Teva's proposed construction.

365. Cipla's ANDA Product comprises a dose counter, which has (what Cipla refers to as) a "units display ring" (6) and "tens cone" (7).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

366. In my opinion, Cipla's ANDA Product comprises a number of components, each of which satisfies the requirements of the claimed dosage indicator: (1) Cipla's units display ring; (2) Cipla's tens cone; and (3) Cipla's units display ring and tens cone. Both individually

and collectively, each of those components display information regarding the number of doses remaining. As their names suggest, Cipla's units display ring displays the units (i.e., ones) digit of the number of doses remaining, and the tens cone displays the tens digit of the number of doses remaining. Thus, at any number of doses remaining, Cipla's units display ring and tens cone collectively display the number of doses remaining. When fewer than ten doses remain, the units display ring also individually displays the number of doses remaining. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

367. [redacted]

368. **Defendants' Proposed Construction.** In my opinion, Cipla's ANDA Product also satisfies this limitation under Defendants' proposed construction, both literally and under the doctrine of equivalents.

369. Defendants' proposed construction requires the counter display to be a "structure

displaying the number of doses remaining." In my opinion, Cipla's dose counter literally comprises such an element, and even if it does not, it comprises an equivalent of this element.

370. As explained above in connection, with Teva's proposed construction, Cipla's ANDA Product comprises (what Cipla refers to as) a "units display ring" and "tens cone." At any number of doses remaining, Cipla's units display ring and tens cone collectively display the number of doses remaining. Additionally, when fewer than ten doses remain, the units display ring also individually displays the number of doses remaining. Thus, both individually and collectively, Cipla's units display ring and tens cone display the number of doses remaining. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

371. Alternatively, even if, contrary to my opinion, Cipla's units display ring and tens cone do not literally qualify as a "counter display," they qualify as a "counter display" under the doctrine of equivalents. The '808 Patent describes that, in certain embodiments, the invention comprises a "counter display," which is arranged to display dosage information. *See, e.g.*, '808 Patent, Abstract, 2:44-4:50, 8:31-9:37, 13:5-54, 15:15-33, 16:5-17:11, 20:14-21:48, Figs. 4A, 6A-6H, 8A-8D, 10A-10F, 21-25. In some of those embodiments, the counter display further comprises a display "tape" that is wound between two "shafts." *See, e.g.*, '808 Patent, Abstract, 2:44-4:50, 8:31-9:37, 13:5-54, 15:15-33, 16:5-17:11, 20:14-21:48, Figs. 4A, 6A-6H, 8A-8D, 10A-10F, 21-25. From those disclosures, POSA would understand that the counter display was an element of the device that informed the patient of the number of doses remaining, by providing an updated number of doses when the patient used the inhaler, to display the current number of doses remaining.

372. The POSA would further understand that the precise strategy used to display the

number of doses remaining was not an essential aspect of the invention as a whole. To that end, the POSA would note that the '808 Patent's discussion of the problems solved by the inventions were not specific to any particular strategy of displaying the number of doses remaining (e.g., using a display tape or shafts). *See, e.g.*, '808 Patent, 2:13-38. Thus, to the extent that a dose counter used a different strategy to display the number of doses remaining, the POSA would understand that to be inessential.

373. In my opinion, to the extent that they do not literally qualify as a "counter display," Cipla's units display ring and tens cone are insubstantially different from one. As explained above, at any number of doses remaining, Cipla's units display ring and tens cone collectively inform the patient of the number of doses remaining by providing an updated number of doses when the patient uses the inhaler, to display the current number of doses remaining. Additionally, when fewer than ten doses remain, Cipla's units display ring satisfies each of these requirements. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings). To the extent that the strategy used in Cipla's device is different from the one used by certain embodiments in the '808 Patent, the POSA would understand those differences to be insubstantial.

374. Alternatively, Cipla's units display ring and/or tens cone and the claimed "counter display" perform substantially the same function in substantially the same way to obtain the same result. At the relevant number of doses remaining, all inform the patient of the number of doses remaining, by way of providing an updated number of doses when the patient uses the inhaler, to obtain the result of displaying the current number of doses remaining. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-

BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

375. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection of Cipla's ANDA Product confirms that (1) Cipla's ANDA Product comprises (what Cipla refers to as) a "units display ring" and "tens cone"; (2) at any number of doses remaining, Cipla's units display ring and tens cone collectively display the number of doses remaining; and (3) when fewer than ten doses remain, Cipla's units display ring displays the number of doses remaining. *See, e.g.*, Cipla Samples.

376. Notwithstanding Defendants' proposed claim construction, Cipla does not contend non-infringement of this limitation. *See* Cipla Non-Infringement Contentions,'808 Patent, Claim 1.

2) "A Drive System Arranged to Move the Counter Display Incrementally in a First Direction From a First Station to a Second Station in Response to Actuation Input"

377. In my opinion, Cipla's ANDA Product comprises a dose counter having "a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to an actuation."

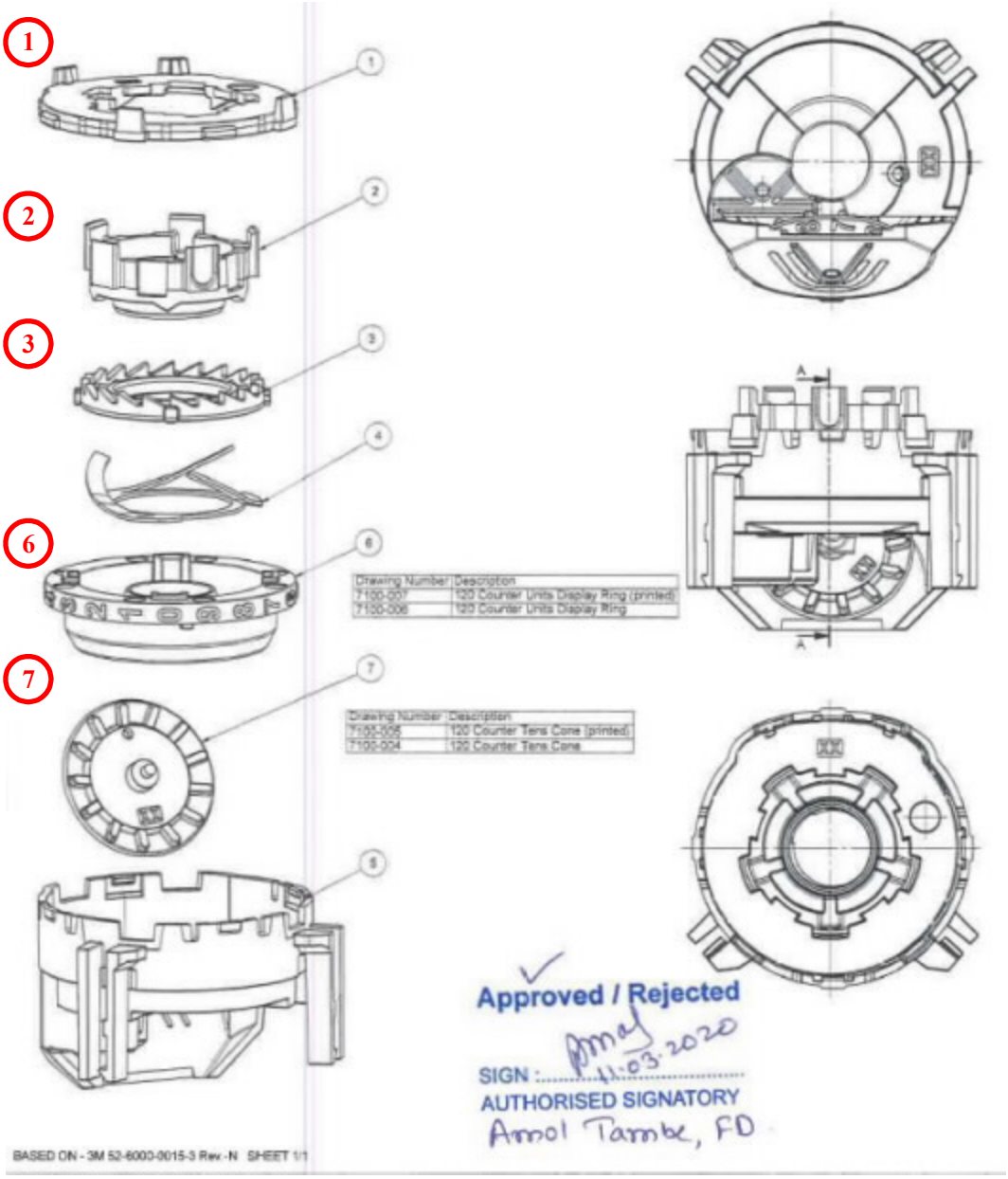
378. I have been informed that the parties have agreed that the term "first direction" should be construed to mean a "single direction at a time." I have applied this construction in my analysis.

379. I have been informed that the parties have proposed different constructions for the terms "first region" and "second region." I have been informed that Teva proposes that the terms should be construed according to their plain and ordinary meanings, in view of the claims, specification, and prosecution history, to mean "a first region" and "a second region,"

respectively. I have been informed that Defendants propose that the terms should be construed to mean a "first structure on which the counter is located" and a "second structure, separate from the first structure, to which the counter display is moved," respectively. I have not been asked to provide an opinion about which constructions are correct, and I express no opinion on that issue. Nevertheless, in my opinion, Cipla infringes under any of the proposed constructions.

380. **Teva's Proposed Constructions.** In my opinion, Cipla's ANDA Product literally satisfies this limitation under Teva's proposed construction.

381. Cipla's ANDA Product comprises a dose counter having (what Cipla refers to as) a "lid" (1), "indexer" (2), "units teeth ring" (3), "units display ring" (6), and "tens cone" (7).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

382. When a patient presses down on Cipla's medicament canister (i.e., actuates Cipla's ANDA Product), the medicament canister presses down on the indexer, and the drive system—i.e., the lid, indexer, and units teeth ring—work together to transmit the downward

motion of the medicament canister to move the units display ring and tens cone. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

383. As I explain in the Section above, Cipla's ANDA Product comprises a number of components, each of which satisfies the requirements of the claimed dosage indicator, including (1) Cipla's units display ring; (2) Cipla's tens cone; and (3) Cipla's units display ring and tens cone. As illustrated below, Cipla's units display ring and tens cone are arranged such that the numbers on those components align along the components' tangent. Each time a patient presses down on Cipla's medicament canister, the units display ring moves incrementally in a single direction from a first region to a second region along that tangent. Additionally, every ten times the patent presses down on Cipla's medicament canister, Cipla's tens cone also moves incrementally in a single direction from a first region to a second region along that tangent.

See, e.g., [redacted] *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

384. As illustrated above, in Cipla's ANDA Product the first position corresponds to the region(s) of the dose counter that are occupied by the current ones and/or tens digits; the second position corresponds to the region(s) of the dose counter that encompass the ones and/or tens digits after they increment. Thus, when Cipla's ANDA Product is at full capacity, the first position corresponds to the region(s) of the dose counter that are occupied by digits"0" (in the case of the units display ring) and/or "12" (in the case of the tens cone); the second position corresponds to the region(s) of the dose counter that are occupied by the digit "1" (in the case of the units display ring) and/or no digit (in the case of the tens cone). *See, e.g.*, [redacted] *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

385. The '808 Patent confirms this analysis. The '808 Patent describes that, in certain embodiments, the counter display consists of a tape that moves between two shafts. '808 Patent, 8:44-50, 11:35-36, Figs. 8A-8D, claim 2 ("2. The dose counter as claimed in claim 1 in which the counter display comprises a tape."). When a patient views the counter display of the assembled inhaler and uses the device, the counter display moves in a direction (solid arrows) that is perpendicular to the patient's viewing angle (dashed arrows).

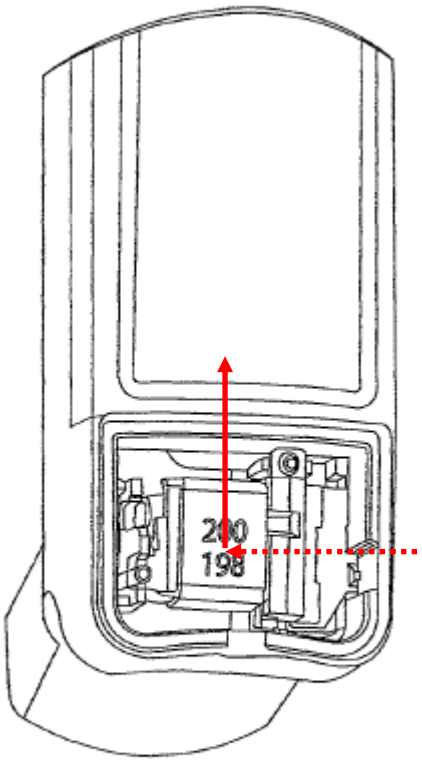


FIG. 8C

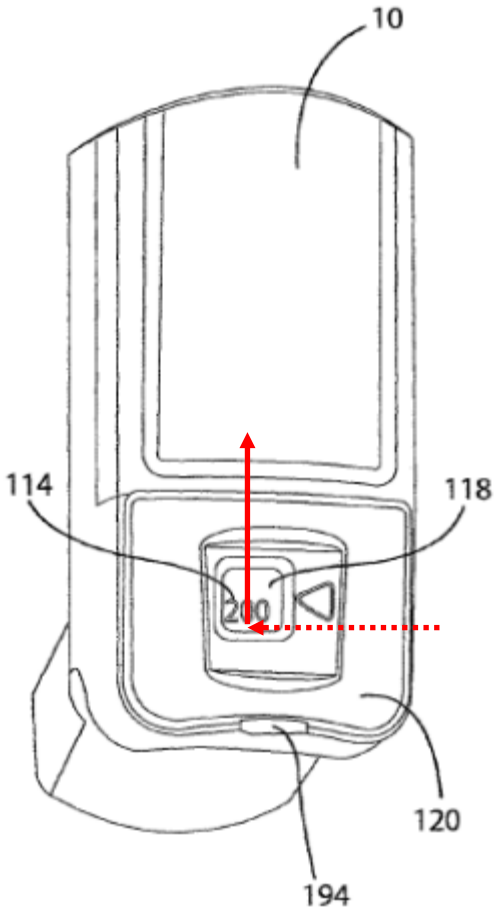


FIG. 8D

'808 Patent, Figs. 8C, 8D. As described above, each of Cipla's units display ring and tens cone likewise moves in a direction that is perpendicular to the patient's viewing angle when a patient uses the device. *See, e.g.*, [redacted] Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

386. [redacted]

387. **Defendants' Proposed Constructions.** Cipla's ANDA Product also satisfies this limitation under Defendants' proposed constructions, at a minimum, under the doctrine of equivalents.

388. Defendants' proposed construction is similar to Teva's, but requires the "first station" and "second station" be a "first structure on which the counter is located" and a "second structure, separate from the first structure, to which the counter display is moved," respectively. In my opinion, at a minimum, Cipla's ANDA Product comprises the equivalents of these elements.

389. The '808 Patent describes that the first station and second station provide two

locations (in Defendants' terms, "structures") from which the counter display moves in response to actuation input. *See, e.g.*, '808 Patent, 2:44-4:50. Thus, the POSA would understand that the first station and second station facilitate the counter display's informing the patient of the number of doses remaining, by providing starting and ending points for the counter display, to facilitate the counter display's displaying the number of doses remaining.

390. The POSA would further understand that, in certain embodiments, the '808 Patent states that the dose counter comprises a display tape and that, in some of those embodiments, the first station and second station are associated with a first shaft and a second shaft, between which the display tape is wound. *See, e.g.*, '808 Patent, 2:44-4:50. However, given the breadth of the '808 Patent's disclosures regarding the first station and the second station, *see, e.g.*, '808 Patent, 2:44-4:50, the POSA would understand that the design of the first station and second station would depend on the specific implementation of the counter display. Thus, the POSA would understand that to the extent that the '808 Patent describes the regulator as associated with a first shaft and a second shaft, that was not an essential aspect of the inventions. Likewise, the POSA would understand the movement of the counter display (whether linear, rotational, or separately defined for multiple components) to be inessential.

391. In my opinion, to the extent that Cipla's ANDA Product does not literally comprise a "counter display" that moves from a "first station" to a "second station" in a first direction, the movement of Cipla's tens cone and/or units display ring between the above-identified regions is insubstantially different from the claimed movement. Although Cipla's ANDA Product does not literally comprise a display tape moving from one shaft to another, like the shafts described in certain examples, the movement of Cipla's counter display facilitates its informing the patient of the number of doses remaining, by providing starting and ending points

for the counter display.

392. Alternatively, in my opinion, the movement of Cipla's tens cone and/or units display ring between the above-identified regions and the claimed movement perform substantially the same function in substantially the same way to obtain the same result. Both perform substantially the same function of facilitating the counter display's informing the patient of the number of doses remaining, by way of providing starting and ending points for the counter display, to obtain the result of facilitating the counter display's displaying the number of doses remaining. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

393. Cipla contends that it does not infringe this limitation because, purportedly, (1) Cipla's ANDA Product uses "two printed, rotating wheels to display the dose count" (i.e., Cipla's tens cone and units display ring) and "does not move from one structure to a second structure, but rather rotates in place"; and (2) both Cipla's tens cone and display ring "are necessary to convey meaningful dosage information to a patient," but "rotate relative to one another, in opposite directions" and therefore do "not move in 'first direction.'" Cipla Non-Infringement Contentions, '808 Patent, Claim 1. I disagree. Cipla's contention that (1) Cipla's tens cone and unit display ring do not "move from one structure to a second structure" and "rotate in place," merely repeats Defendants' claim construction position. As I explain above, at a minimum, Cipla's ANDA Product comprises the equivalents of a first and second structure. Additionally, Cipla's contention that (2) Cipla's tens cone and display ring "are necessary to convey meaningful dosage information to a patient," but "rotate relative to one another, in opposite directions" ignores that each can be considered a counter display and, in any event, move in a manner that is equivalent to the claimed "first direction."

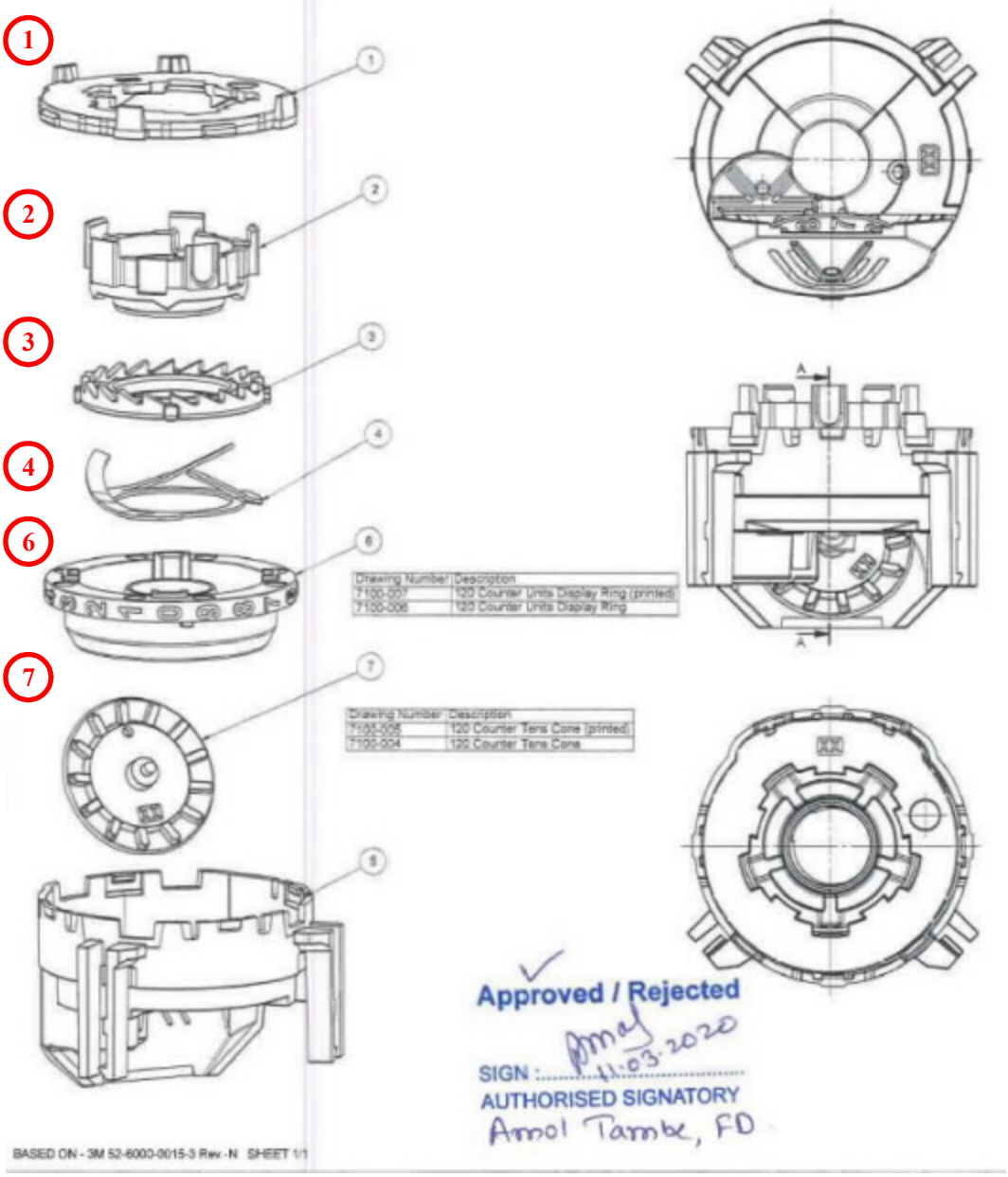
394. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises (what Cipla refers to as) a "units display ring" and "tens cone"; (2) at any number of doses remaining, Cipla's units display ring and tens cone collectively display the number of doses remaining; (3) when fewer than ten doses remain, Cipla's units display ring displays the number of doses remaining; and (4) when Cipla's dose counter actuates, Cipla's units display ring and/or tens cone move incrementally in a first direction from a first region to a second region. *See, e.g.*, Cipla Samples.

c. "Wherein a Regulator Is Provided Which Is Arranged to Act Upon the Counter Display at the First Station to Regulate Motion of the Counter Display at the First Station to Incremental Movement"

395. In my opinion, Cipla's ANDA Product comprises a "regulator which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movement."

396. I have been informed that the parties have agreed that the term "regulator" should be construed to mean "a structure of the dose counter that modulates motion of the counter display"; and that the term "regulate motion of the counter display" should be construed to mean "modulate motion of the counter display." I have applied those constructions in performing my analysis.

397. Cipla's ANDA Product comprises a dose counter having (what Cipla refers to as) a "lid" (1), "indexer" (2), "units teeth ring" (3), "leaf spring" (4), "units display ring" (6), and "tens cone" (7).



See, e.g., CIPLA-BDI_0156579 (Design Drawings); *see also* Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0803837-38 (Design Drawings).

398. When a patient presses down on Cipla's medicament canister, the medicament canister presses down on the indexer, which engages with the units teeth ring, causing it to rotate. In turn, the units teeth ring causes the units display ring and tens cone to rotate.

Consistent with its description as a "spring," Cipla's leaf spring sits between Cipla's dose counter components and regulates (i.e., modulates) the movement of the units display ring and tens cone to incremental input, including at the first position That is, as the patient presses down on the medicament canister, the leaf spring applies a resistance force against the medicament canister in the opposite direction of its downward motion and, consequently, in the opposite direction of the units display ring's and tens cone's motion. As a result, the patient must perform a sufficient amount of work (i.e., a sufficient amount of force over a sufficient distance) to cause the dose counter to count. After Cipla's dose counter actuates (i.e., counts), the leaf spring applies a restoring force against the medicament canister, and, consequently, the units display ring and tens cone, which helps prevent the dose counter from counting a second time. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

399. Exhibit C describes experiments measuring the amount of force and distance needed to cause Cipla's ANDA Product to fire and count, which further illustrates those principles. In connection with those experiments, I measured the resistive force of Cipla's leaf spring. Below, I reproduce those results.

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Mean ± Standard Deviation (n=5)

Distance (mm)	Force (N)
0.132 ± 0.004	0.118 ± 0.004
0.307 ± 0.003	0.534 ± 0.005
0.488 ± 0.004	1.030 ± 0.007
0.847 ± 0.003	2.028 ± 0.004
1.221 ± 0.015	3.036 ± 0.009
1.554 ± 0.004	4.036 ± 0.009
1.927 ± 0.025	5.030 ± 0.007
2.250 ± 0.012	6.050 ± 0.007
2.468 ± 0.008	7.048 ± 0.008
2.667 ± 0.010	8.062 ± 0.013

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Mean ± Standard Deviation (n=5)

Distance (mm)	Force (N)
0.144 ± 0.004	0.112 ± 0.004
0.315 ± 0.002	0.532 ± 0.004
0.496 ± 0.002	1.030 ± 0.000
0.881 ± 0.007	2.034 ± 0.005
1.315 ± 0.022	3.024 ± 0.005
1.707 ± 0.030	4.028 ± 0.004
2.029 ± 0.011	5.040 ± 0.000
2.280 ± 0.008	6.052 ± 0.011
2.523 ± 0.018	7.062 ± 0.015
2.684 ± 0.019	8.046 ± 0.009

As the results above demonstrate, Cipla's leaf spring provides a resistive force against the downward movement of Cipla's medicament canister (which causes Cipla's counter display to move), which increases as the medicament canister moves downward. This classic, spring-like behavior reflects the contributions of Cipla's leaf spring to the incremental movement of its units display ring and tens cone.[5]

[5] Additionally, as part of the same experiments, I measured the amount of force and

400. The '808 Patent confirms this analysis. The '808 Patent describes that the regulator modulates movement of the counter display, by applying (1) a resistance force opposite to the direction of the motion of the counter display before it counts and (2) a restoring force in the direction of the motion of the counter display after it counts, to help prevent the dose counter from counting a second time. *See, e.g.*, '808 Patent, 2:44-4:50, 17:62-20:11, Figs. 15-20. In other words, the regulator exhibits classic, spring-like behavior. Cipla's regulator (i.e., what Cipla refers to as a "leaf spring") is to the same effect. Like the examples of the regulators described in the patent, Cipla's regulator applies (1) a resistance force opposite to the direction of the motion of the counter display before it counts and (2) a restoring force in the direction of the motion of the counter display after it counts. *See, e.g.*, Cipla Samples; CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report); CIPLA-BDI_0156579; CIPLA-BDI_0803837-38 (Design Drawings).

401. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies this limitation. For example, physical inspection confirms that (1) Cipla's dose counter comprises a regulator (i.e., what Cipla refers to as a "leaf spring"); (2) Cipla's regulator regulates the motion of Cipla's counter display (i.e., what Cipla refers to as the "units display ring" and/or "tens cone") at a first station to incremental movement; (3) when a patient presses down on Cipla's medicament canister, Cipla's regulator provides a resistance force in the opposite direction of Cipla's counter display; and (4) when Cipla's dose counter actuates (i.e.,

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distance needed to cause Cipla's ANDA Product to fire and count when the medicament canister is removed. As those experiments illustrate, Cipla's dose counter components continue to provide a resistive force against the downward motion of the medicament canister (which causes Cipla's counter display to move) even in the absence of the valve stem. That provides further evidence of the contributions of Cipla's leaf spring in regulating the movement of Cipla's counter display.

counts), Cipla's regulator provides a restoring force in the direction of Cipla's counter display.

402. Cipla contends that it does not infringe this limitation because, purportedly, Cipla's ANDA Product does not comprise a "first station." *See* Cipla Non-Infringement Contentions, '808 Patent, Claim 1. I disagree for the reasons stated in connection with the Section above. *See, e.g.*, *supra* Section VIII.D.1.b.2) ('808 Patent, Claim 1).

2. '808 Patent, Claim 27

403. Claim 27 of the '808 Patent recites: "The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

404. In my opinion, Cipla's ANDA Product satisfies the limitations of claim 1, as explained above. *See, e.g.*, *supra* Section VIII.D.1 ('808 Patent, Claim 1). As explained, Cipla's dose counter has a regulator (i.e., what Cipla refers to as a "leaf spring"), which provides a resistance force against movement of the counter display. [redacted] Because Cipla's leaf spring provides the same resistive force against Cipla's counter display that it does against Cipla's medicament canister, this evidence shows that Cipla's ANDA Product applies a resistance force of greater than 0.1 N against movement of the counter display.

405. The force-displacement experiments described in Exhibit C and in connection with claim 1 of the '808 patent above confirm this analysis. As the results reproduced in connection with claim 1 demonstrate, Cipla's leaf spring applies a resistive force of greater than 0.1 N against movement of the counter display. *See, e.g.*, *supra* Section VIII.D.1.c ('808 Patent,

Claim 1).

406. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises a regulator (i.e., what Cipla refers to as a "leaf spring"); and (2) Cipla's regulator provides a resistance force against the movement of Cipla's counter display (i.e., what Cipla refers to as a "units display ring" and/or "tens cone"). *See, e.g.*, Cipla Samples.

407. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1, 2, 4, and 23 of the '808 Patent. *See* Cipla Non-Infringement Contentions,'808 Patent, Claim 27. Claim 27 does not depend from any of claims 2, 4, and 23, and I do not understand why Cipla believes its contentions regarding those claims to be relevant. I further disagree with Cipla for the reasons stated in connection with claim 1. *See, e.g.*, *supra* Section VIII.D.1 ('808 Patent, Claim 1).

3. '808 Patent, Claim 28

408. Claim 28 of the '808 Patent recites: "The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N." In my opinion, Cipla's ANDA Product satisfies every limitation of this claim.

409. In my opinion, Cipla's ANDA Product comprises a dose counter that meets the limitations of claim 27, as described above. In my opinion, the same evidence shows that Cipla's ANDA Product comprises a dose counter in which the resistance force is greater than 0.3 N. *See, e.g.*, *supra* Sections VIII.D.1.c, VIII.D.2 ('808 Patent, Claims 1, 27).

410. Physical inspection of Cipla's Samples further confirms that Cipla's ANDA Product satisfies the limitations of this claim. For example, physical inspection confirms that (1) Cipla's ANDA Product comprises a regulator (i.e., what Cipla refers to as a "leaf spring"); and (2) Cipla's regulator provides a resistance force against the movement of Cipla's counter

display (i.e., what Cipla refers to as a "units display ring" and/or "tens cone"). *See, e.g.*, Cipla Samples.

411. Cipla contends that it does not infringe this claim for the same reasons that it contends that it does not infringe claims 1, 2, 4, 23, and 27 of the '808 Patent. *See* Cipla Non-Infringement Contentions,'808 Patent, Claim 28. Claim 28 does not depend from any of claims 2, 4, and 23, and I do not understand why Cipla believes its contentions regarding those claims to be relevant. I further disagree with Cipla for the reasons stated in connection with claims 1 and 27. *See, e.g.*, *supra* Sections VIII.D.1, VIII.D.2 ('808 Patent, Claims 1, 27).

IX. Objective Indicia of Non-Obviousness

412. I have been informed that a patent claim is invalid for obviousness if the differences between the invention it claims and the prior art are such that the invention as a whole would have been obvious to the POSA at the time the invention was made. I have been informed that analysis of whether a claim would have been obvious depends on (a) the scope and content of the prior art, (b) the differences between the claimed invention and the prior art, (c) the level of ordinary skill in the art, and (d) any secondary considerations of non-obviousness. I have been informed that the use of hindsight must be avoided because the obviousness of an invention is evaluated from the perspective of the POSA at the time the invention was made. Thus, in conducting an obviousness inquiry, one must be aware of the distortion caused by hindsight bias and must be cautious to avoid reading into the prior art the teachings of the claimed invention at issue.

413. I have been informed that a proper obviousness analysis involves an evaluation of any secondary considerations of non-obviousness, also referred to as "objective indicia of non-obviousness." I have been informed that commonly recognized objective indicia include, among others, evidence of long felt but unsolved needs, failure of others, industry acceptance, and

praise. I have been informed that the consideration of such objective indicia guards against hindsight bias and that, in appropriate circumstances, evidence of objective indicia may be determinative of the ultimate question of obviousness. I have been informed that any objective indicia must have a sufficient nexus to the claimed invention(s); that is, the objective indicia must sufficiently relate to the novel aspects of those invention(s).

A. Long-Felt, Unmet Need

414. In my opinion, the inventions recited in the Asserted Claims satisfied multiple, long-felt needs, which provides further evidence that those inventions would not have been obvious. As I explain below in greater detail, as of the priority dates, there were multiple, long-felt, unmet needs for inhalers with dose counters having the properties of the claimed inventions, including the need for inhalers with dose counters having sufficient functionality, accuracy (including, with respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors).

1. The Prior Art Recognized Needs for Inhalers With Dose Counters Having the Properties of the Claimed Inventions.

415. As of the priority dates, no inhalers with dose counters had the combination of properties possessed by the inventions recited in the Asserted Claims. Indeed, the prior art recognized that, in many cases, inhalers did not include any dose indicating mechanisms (e.g., a dose counter or dose indicator) whatsoever. In the absence of such mechanisms, patients were left to devise a number of methods for attempting to determine the number of doses remaining, including (1) shaking the inhaler; (2) test-firing the inhaler; (3) placing the inhaler in a bowl of water; (3) attempting to "taste" differences in the spray; and (4) counting the number of doses on a piece of paper. *See, e.g.*, Fink 2005, CIPLA-BDI_0184184, at -189; Holt 2005, at 105-06;

Ogren 1995, TEVADOC-00000011, at -13-15; Sander 2006, TEVADOC-00000046, at -48-49.

416. However, each of these methods was highly inaccurate. *See, e.g.*, Fink 2005, CIPLA-BDI_0184184, at -189 ("To mitigate the risk of a patient continuing to use an 'empty' inhaler, pharmaceutical manufacturers instruct patients to count their inhaled doses over the life of the canister. This is inconvenient, impractical, unrealistic, and unreliable. Most patients simply do not keep a running tally of the doses used, especially with their reliever medications. In the past, some pMDI manufacturers had suggested floating the canister (without boot) in a bowl of water as a rough indicator to determine remaining contents. Not only does this not work reliably, but water entering the nozzle can radically reduce the subsequent dose, so floating the canister is no longer a recommended technique by most in the industry."); Holt 2005, at 105-06; Ogren 1995, TEVADOC-00000011, at -13-15; Sander 2006, TEVADOC-00000046, at -50 ("[P]atients do not have a reliable means of monitoring the contents of their metered-dose inhalers. It is well known and uncontested that shake testing and spray testing are misleading, and the flotation method has been repeatedly shown to be both inaccurate and potentially damaging to the product. The only FDA-approved approach is for patients to keep track of doses as they use them, but demanding a practice as cumbersome as this is impractical."); '289 Patent, 1:49-54 ("A drawback of self-administration from an inhaler is that it is difficult to determine how much active drug and/or propellant are left in the inhaler, if any . . . .").

417. Even counting the number of doses on a piece of paper—the only FDA-approved method for determining the number of remaining doses—was too impractical to use effectively and, as a consequence, suffered from poor compliance. *See, e.g.*, Sander 2006, TEVADOC_00000046, at -49-50 ("The FDA recommends that patients keep a diary of inhaler use and discard the inhaler on reaching the labeled number of doses, even though the inhaler may

appear to continue delivering medication. This method, however, is cumbersome and issues of compliance render it wholly impractical, especially for patients using their pMDI on an irregular basis, as with bronchodilators. In one survey, only 8% of respondents determined when to replace their pMDI by counting the number of actuations used."); Fink 2005, CIPLA-BDI_0184184, at -189 ("To mitigate the risk of a patient continuing to use an 'empty' inhaler, pharmaceutical manufacturers instruct patients to count their inhaled doses over the life of the canister. This is inconvenient, impractical, unrealistic, and unreliable. Most patients simply do not keep a running tally of the doses used, especially with their reliever medications."); '289 Patent at 1:49-54.

418. [redacted]

419. The prior art recognized several problems caused by the lack of adequate inhalers with dose counters. In particular, commentators noted that patients faced the undesirable choice of either (1) discarding inhalers that still contained remaining doses, resulting in waste; or (2) using inhalers that did not contain any doses, risking death or other serious injury. *See, e.g.*, Holt 2005, at 106 ("These findings confirm that patients are unable to determine when an MDI should be discarded, resulting in insufficient drug delivery at the end of the life of an MDI for the

majority of patients, and wastage of the drug for others."); Sander 2006, TEVADOC-00000046, at -50 ("It is wholly unacceptable that so many patients, believing they are equipped with the means to manage their asthma and life-threatening episodes, are actually using an empty inhaler and putting their lives at risk simply because they do not know whether their inhaler contains medication and have no way of making that determination."); Ogren 1995, TEVADOC-00000011, at -14-15 ("We believe the combination of using an inaccurate technique for determining when to replace a metered-dose inhaler and the large number of actuations that may remain beyond the number of listed by a manufacturer clearly means that many asthmatic patients are utilizing actuations that may not contain accurate doses of medications. . . . The implications of these data are worrisome [and] potentially serious . . . ."); Fink 2005, CIPLA-BDI_0184184, at -189; Hess at 710; '289 Patent at 1:49-54.

420. In 2003, in recognition of the need for dose counters with these properties, FDA published guidance providing non-binding recommendations regarding the integration of dose counters and dose indicators in metered dose inhalers. In particular, FDA recommended "that manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product." FDA Guidance 2003, TEVAQVAR-00032573, at -578.

421. FDA provided additional, specific recommendations, including:

- Dose counters should provide, either through a direct numeric count or color coding, a clear indication of when an MDI is approaching the end of its recommended number of actuations as well as when it has reached or exceeded that number. An indication that an MDI is approaching the end of its recommended number of actuations should occur when a sufficient number of actuations are left to give patients enough time to obtain a new MDI. If a numeric count is chosen, we recommend that the counter be designed so that it counts downward from the recommended number of actuations to zero, rather than counting upwards, enabling patients to know when a device is approaching the end of its life (i.e., the number of actuations is approaching zero).

- Dose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible. However, if some low frequency of error is unavoidable, the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance). Undercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.

- The reliability of dose counters should be established during development under in-vitro testing (simulating use and potential abuse), as well as in clinical use. The documentation of dose counter functionality, reliability, and accuracy would ideally be derived from assessments in clinical trials including, where possible, phase-3 trials. However, for dose counters added either late in a development program or postapproval, in-use studies should be designed and conducted to obtain this information.

FDA Guidance 2003, TEVAQVAR-00032573, at -578-79.

422. Echoing commentators' concerns, FDA explained, "Currently available MDIs offer no practical way for patients to track the remaining numbers of doses or amount of medication." FDA Guidance 2003, TEVAQVAR-00032573, at -577. Thus, "patients must guess how many doses are left in their MDIs and have two practical options: (1) throw away an MDI that may still contain acceptable metered-doses or (2) use a product when it may be beyond the recommended number of doses and risk not receiving the correct drug dose. The former is wasteful, and the latter is potentially dangerous. The addition of an accurate dose counter to an individual MDI unit would allow the patient to reliably track the numbers of actuations used from that individual inhaler (i.e., to identify when the label claim number of actuations has been reached). This would prevent the patient from discarding an inhaler unnecessarily or using the product beyond the recommendations provided in the labeling for that product." FDA Guidance 2003, TEVAQVAR-00032573, at -577.

423. As I explain below in greater detail, in my opinion, the successes of the inventions recited in the Asserted Claims in satisfying these long-felt, unmet needs, alone and in combination with one or more other needs, provides further evidence that those inventions would

not have been obvious.

2. The Prior Art Failed to Satisfy Those Needs.

424. Despite FDA's and commentators' concerns, however, prior art efforts to develop improved dose counting mechanisms failed to satisfy the needs for dose counters having the properties of the inventions recited in the Asserted Claims.

425. **Use of Dose Indicators.** As an initial matter, many prior art devices incorporated dose indicators, rather than dose counters. Unlike dose counters, dose indicators provide only a general indication of the number of doses remaining, for example, by displaying the number of doses in multiples of ten or by using colors. Although attractive because of their lower cost to design and manufacture, they traded cost for accuracy. *See, e.g.*, Stuart 2013, at 41 ("A typical dose counter has a numerical display, indexes forward for each actuation made and has a discrete display – factors that often lead to preference by patients over a dose indicator. Dose indicators take many forms, but often count in multiples (for example, 10 or 20) or use colours to display remaining doses (see Figure 1). They often do not index every count and require some patient interpretation of the display. The appeal of dose indicators tends to be the larger display and lower cost, although they are not considered by patients to be as accurate as a dose counter."); Conner 2013, at 661 ("Dose indicators that rely solely on a color coded display or indicator symbol are less precise than dose counters that use a numeric display . . . ."); '289 Patent, 2:9-12. In the Section below, I describe examples of such devices, including ones developed by Aptar France S.A.S. ("Aptar")/Valois S.A.S. ("Valois"), AstraZeneca Pharmaceuticals LP ("AstraZeneca"), Bespak, Senetics, Inc. ("Senetics"), Inc., Sapphire Designs, Inc. ("Sapphire Designs"), and Trudell Medical International, Inc. ("Trudell Medical").

426. **Placement of the Dose Counter or Dose Indicator.** Many prior art dose counters and dose indicators suffered from problems caused by the placement of the dose counter

or dose indicator relative to the inhaler's other components. As a result of these problems, many dose counters and dose indicators that were theoretically capable of accurately recording and displaying information, failed as a result of the practical realities of patient use.

427. To avoid addressing the challenges of incorporating a dose counter or dose indicator into the inhaler body, many prior art devices attempted to provide "add-on" dose counters or dose indicators, which could be attached to the outside of existing inhalers without interacting with any of those inhalers' internal components. While superficially attractive, such add-on approaches suffered from increased expense and decreased usability, because of their bulkiness. In addition, many of these approaches suffered from decreased accuracy and compatibility. *See, e.g.*, Fink 2005, CIPLA-BDI_0184184, at -189 ("Third party dose counting devices are available, but add additional expense."); Hess 2008, at 710-11 ("An issue that has not been adequately addressed with these add-on dose counting devices is patient satisfaction. For example, they add to the cost of therapy and they increase the complexity of therapy because they add a device to the treatment regimen. Some of the devices, such as MD Turbo, are also not compatible with spacers and VHCs."); Kennedy 2015, at 4 ("The introduction of externally mounted dose counters or indicators can require significant changes to the actuator's external dimensions, resulting in a bulky profile. A top mounted dose counter or indicator extends the hand span required for operation."). In the Section below, I discuss examples of such devices, including ones developed by Meditrack Products, Inc. ("Meditrack Products"), and Respirics, Inc. ("Respirics")/Teamm Pharmaceuticals Inc. ("Teamm Pharmaceuticals").

428. In a similar fashion, many prior art devices placed the dose counter or dose indicator on top of the medicament canister (from the perspective of the patient looking downwards on the assembled device). Because they exposed the dose counter or dose indicator,

however, such top-mounted approaches suffered from increased tampering and decreased robustness, as a result of intentional or accidental damage, for example, caused by accidental dropping. *See, e.g.*, Stuart 2013, at 41 ("Top-mounted dose counters or indicators are attached to the MDI canister. An advantage of a top-mounted device is that it can be added to a design without affecting existing components or pre-existing drug delivery. The two disadvantages are the overall height of the MDI, which is extended and has the potential to create difficulty for patients with a limited hand span; and the fact that the counter itself is exposed to the patient, which therefore means it must be designed to withstand a higher level of tampering and abuse."); '289 Patent, 2:6-8 ("[S]ome dose counters do not keep a particularly reliable count, such as if they are dropped onto a hard surface."). In the Section below, I describe examples of such devices, including ones developed by Aptar/Valois, AstraZeneca, Senetics, and Trudell Medical.

429. Other prior art devices placed the dose counter on the side of the medicament canister or canister housing. However, such side-mounted approaches significantly increased the bulk of the device, reducing patient usability. *See, e.g.*, Stuart 2013, at 41 ("Side-mounted dose counters or indicators can be viewed as a compromise between internal and top-mounted dose counters. Side mounts have the advantages of sitting outside of the airflow, and being enclosed and tamper proof. However, one disadvantage of a side mount is its bulky appearance and size, which patients may find ungainly to use. The addition of a side-mounted dose counter to an existing product can drastically change its appearance, which can have a negative impact on a product where maintaining patient familiarity is essential."). In the Section below, I describe examples of such devices, including ones developed by Aptar/Valois and Sapphire.

430. Still other prior art devices placed the dose counter or dose indicator on the bottom of the medicament canister. By their nature, such bottom-mounted approaches resulted

in limited compatibility with different medicament canister and valve types; thus, although they were used in certain product lines, they failed to provide a general solution to the problem of drug delivery. In the Section below, I describe examples of such devices, including ones developed by GlaxoSmithKline.

431. Yet other devices attempted to integrate the dose counter or dose indicator into the canister housing. However, while this approach avoided the flaws of top- or side-mounting the dose counter or dose indicator, such devices had the potential to disrupt airflow through the device, potentially affecting the resulting spray plume. *See, e.g.*, Stuart 2013, at 41 ("Internal dose counters or indicators sit within the actuator and are often visible to the patient via a window in the actuator (see Figure 2). Fitting a dose counter or dose indicator inside the actuator is a very difficult task, as the space envelope between the MDI valve and actuator is typically very small. An internal dose counter or indicator sits in the upstream airflow of the MDI, which has the potential to disrupt the spray plume. Despite that, the main advantages are that the counter is a contained, tamper-proof system and that the outward appearance of the actuator remains familiar to patients. That means that apart from having an additional viewing window, it has the appearance of a typical MDI."). Qvar® HFA with dose counter and ProAir® HFA with dose counter exemplify such devices. *See, e.g.*, TEVAQVAR-00008706, at -706-08, -714-18 (Qvar® HFA Container Closure System); TEVAQVAR-00052614, -614-16, -619-22 (ProAir® HFA Container Closure System).

432. **Design of the Dose Counter or Dose Indicator.** In addition to problems relating to their placement, many prior art dose counters and dose indicators suffered from problems relating to the design of the mechanisms by which they recorded or displayed information. These problems affected both mechanical and electronic dose counters and dose indicators.

433. Mechanical prior art dose counters and dose indicators contained complex moving parts, which were difficult and expensive to assemble or manufacture. They also suffered from inaccuracy and interfered with airflow. *See, e.g.*, '021 Publication ¶ [0006] ("Some dispensing devices have indicating devices that convert the linear reciprocal movement of the container relative to the housing into a one-way, or single-cycle, movement of an indicator, wherein the indicator identifies the relative fullness of the container, the number of metered doses remaining therein or the number of doses already administered. . . . [I]ndicating devices of this nature may include complex moving parts which can be difficult to assemble and expensive to manufacture. Such devices may also be susceptible to counting inaccuracies due to the configuration of the indexing or mating parts, or require excessive amounts of space within the housing to accommodate the relatively large or numerous moving parts. Others still may impede or interfere with the airflow and medicament being dispensed from the inhalation device.").

434. Electronic prior art dose counters and dose indicators suffered from additional flaws. Among other things, such devices were highly susceptible to environmental damage and were expensive to manufacture. *See, e.g.*, '021 Publication ¶ [0006] ("[S]ome devices use electrical circuitry to count or record the dispersements. Such devices can be relatively expensive to manufacture, however, and typically require a power source which may be susceptible to damage in various environments, such as moist conditions."). In the Section below, I describe examples of such devices, including those developed by Aptar, Nexus6 Ltd. ("Nexus6"), Meditrack Products, and Respirics/Teamm Pharmaceuticals.

3. The Claimed Inventions Satisfied Those Needs.

435. In contrast with prior art, the inventions recited in the Asserted Claims, including as embodied by Qvar® HFA with dose counter and ProAir® HFA with dose counter satisfied the needs for inhalers with dose counters with sufficient functionality, accuracy (including, with

respect to under- and over-counting), reliability, maintainability (and ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including aesthetics, ergonomics, and other human factors).

436. As an initial matter, the inventions recited in the Asserted Claims, including as embodied in Qvar® HFA with dose counter and ProAir® HFA, with dose counter proved to have superior accuracy, reliability, and robustness in comparison with prior art inhalers with dose counters or dose indicators. This is demonstrated, for example, by the results of Teva's accuracy and drop tests for those devices. *See, e.g.*, TEVAQVAR-00765383 (Qvar®HFA Design History File); TEVA-QVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00007440 (Qvar®HFA AccuracyTest); TEVAQVAR-00765418 (Qvar®HFA Engineering Qualification Report); TEVAQVAR-00052614 (ProAir®HFA ContainerClosure System); TEVAQVAR-00761426 (ProAir®HFA Engineering Qualification Report); '289 Patent, Abstract, 2:41-53, 4:30-5:13.

437. Indeed, as part of the research and development project that resulted in the development of ProAir® HFA with dose counter, Teva set and succeeded in achieving the goal of developing a dose counter with a failure rate of less than 50 failed counts per million uses.

TITLE: Teva C2 Actuator – EQ Test Summary Report	DOCUMENT #: 1020172-08	
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Loop #	Test	Condition Group	Requirement Predict less than 50 PPM outside of 186 – 194 strokes to first zero. Defects per million units **Total**	Pass or Fail
Loop 5	TM-0366: Counter Accuracy	Ambient C01-A	0	Pass
		At high temperature C02-A	0	Pass
		At low temperature C03-A	3	Pass
		Drop, 1m C05-A	20,957	Fail
Loop 6	TM-0366: Counter Accuracy	Drop, 1m L4	0.44	Pass
Loop 7	TM-0366: Counter Accuracy	Drop, 1m NL4	237	Fail
Loop 8	TM-0366: Counter Accuracy	Ambient L4C	0.54	Pass

Loop #	Test	Condition Group	Requirement	Results	Pass or Fail
Loop 9	Tape Angle Investigation	NL4 (Loop 7)	Informational only, Testing for correlation	r = .78	N/A
		L4C (Loop 8)	Informational only, Testing for correlation	r = .68	N/A

See, e.g., TEVAQVAR-00761426, at -444-45 (ProAir® HFA Engineering Qualification Report); *see also* TEVAQVAR-00761426, at -431-73; '289 Patent, 4:46-5:13 ("It has been found that dose counters with these features have a failure rate of less than 50 failed counts per million full canister activation depressions."). As a pharmaceutical development scientist in the inhalation aerosol industry, I am frequently asked to establish and review specifications for inhalation products. In my experience, that is an extremely ambitious standard.

438. Additionally, unlike many of the prior art dose counters and dose indicators

discussed in the Section above, the inventions recited in the Asserted Claims, including as embodied in Qvar® HFA and ProAir® HFA, achieved this superior functionality, accuracy, reliability, and robustness, while having minimal impact on device performance or human factors, such as ergonomics or aesthetics. *See, e.g.*, TEVAQVAR-00008706, at -706-08, -714-18 (Qvar® HFA Container Closure System); TEVAQVAR-00010727 (Qvar® HFA Labeling); TEVAQVAR-00764907, at -913-45 (Qvar® HFA Pharmaceutical Comparison); TEVAQVAR-00052614, -614-16, -619-22; TEVAQVAR-00052952 at -966-71 (ProAir® HFA Container Closure System); TEVAQVAR-00066638 (ProAir® HFA Labeling).

439. Similarly, the inventions recited in the Asserted Claims, including as embodied by Qvar® HFA with dose counter and ProAir® HFA with dose counter, succeeded in achieving the above goals, while achieving superior manufacturability and maintainability. These successes are especially notable given that inhalation devices, such as Qvar® with dose counter and ProAir® with dose counter, are consumer-grade products, intended for production and use on a mass scale.[6] In my experience, balancing functionality with manufacturability and maintainability is often one of the most significant design challenges, and many otherwise successful devices fail because they cannot be manufactured or maintained at an acceptable cost.

440. In my opinion, the successes of the inventions recited in the Asserted Claims in satisfying these long-felt, unmet needs, alone and in combination with one or more other needs, provides further evidence that those inventions would not have been obvious.

[6] For example, in 2012, the year in which Teva introduced ProAir® HFA with dose counter, U.S. retail sales of ProAir® HFA amounted to more than 30 million units. *See, e.g.*, Drugs.com, Quarterly ProAir HFA Sales Data & Retail Statistics Information, https://www.drugs.com/stats/proair-hfa.

B. Failure of Others

441. In my opinion, the failure of others to develop inhalers and dose counters having the properties of the inventions recited in the Asserted Claims provides further evidence that those inventions would not have been obvious. As I explain below in greater detail, at or around the priority dates, multiple established pharmaceutical companies (including Aptar, AstraZeneca, Bespak, Cipla, GlaxoSmithKline, Nexus6, Meditrack Products, Respirics, Teamm Pharmaceuticals, Senetics, and Trudell Medical) attempted to develop improved inhalers and dose counters. Despite these efforts, however, none succeeded in achieving an inhaler or dose counter having the properties of the claimed inventions, including those described in the previous Section.

442. **Aptar/Valois.** At around the priority dates, Aptar and its predecessor, Valois, attempted to develop improved dose counters and dose indicators. *See, e.g.*, U.S. Patent Nos. 5,988,496 ("Valois '496"), 7,637,227 ("Valois '227"). However, Aptar and Valois failed to develop a dose counter that could be integrated into the canister housing as a separate component; and instead, developed only product candidates in which a dose indicator was attached to the top or side of the medicament canister.

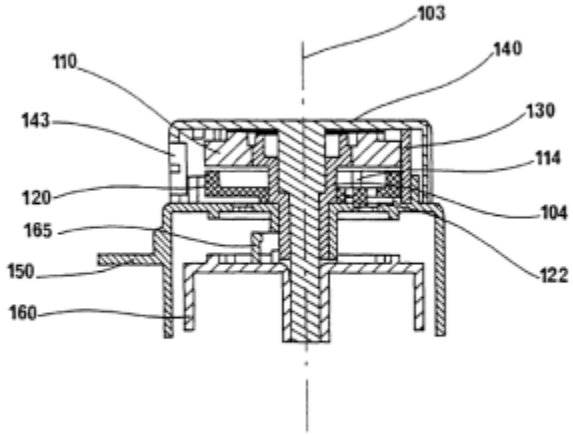


FIG.6

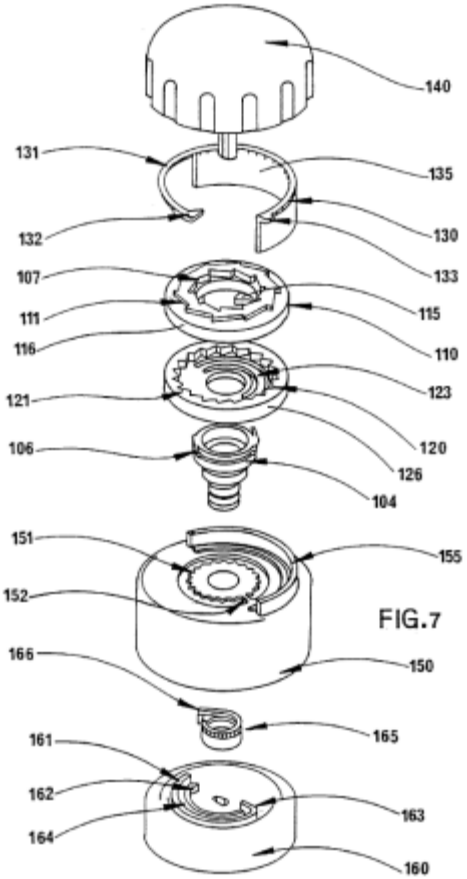


FIG.7

See, e.g., Valois '496, Figs. 6-7.

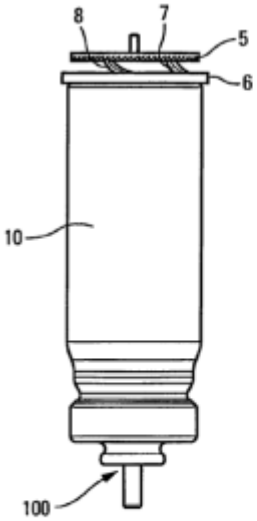


Fig. 8

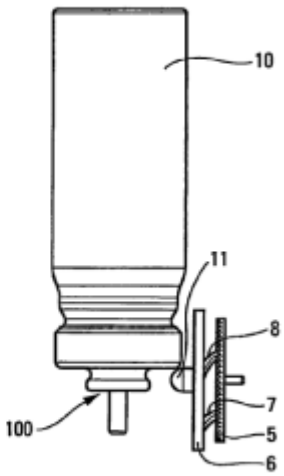


Fig. 9

See, e.g., Valois '227, Figs. 8, 9; 1:49-55 ("More particularly, an object of the present invention is to provide such an indicator . . . that can be disposed in particular on the bottom of the reservoir or on the side of said reservoir regardless of the type of powder or fluid dispenser device."), 3:6-54. As illustrated above, Aptar's and Valois's top- and side-mounted product candidates suffered from the problems associated with similar designs, including because increased the bulkiness of the inhaler, and, in the case of the top-mounted product candidates, increased opportunities for accidental or intentional damage. *See, e.g.*, *supra* Section IX.A.2.

443. Separately, Aptar attempted to develop an electronic dose indicator. *See, e.g.*, U.S. Patent No. 8,267,086 ("Aptar '086").

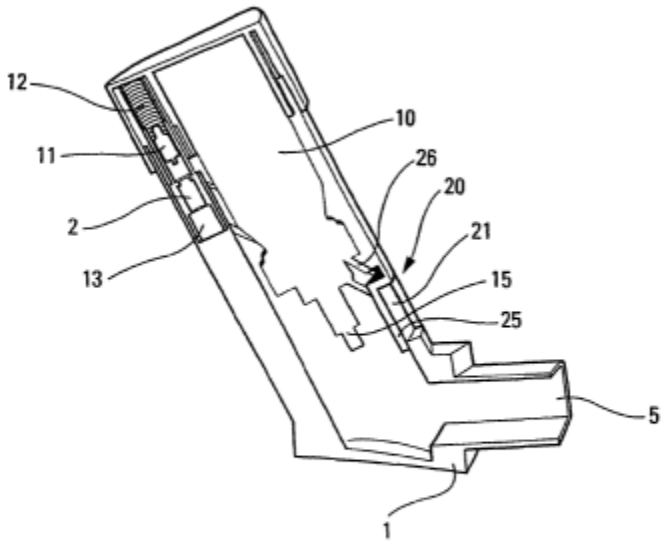


Fig. 3

See, e.g., Aptar '086, Fig. 3, 2:55-4:21. However, Aptar's product candidates inherited the problems of other side-mounted devices and, as typical of electronic devices, lacked robustness and maintainability. *See, e.g.*, *supra* Section IX.A.2.

444. **AstraZeneca.** In 2007, AstraZeneca received approval to add a dose indicator to

Symbicort®, an inhalation drug product indicated for the treatment of certain kinds of asthma. *See* Symbicort Prior Approval Supplement 2007.

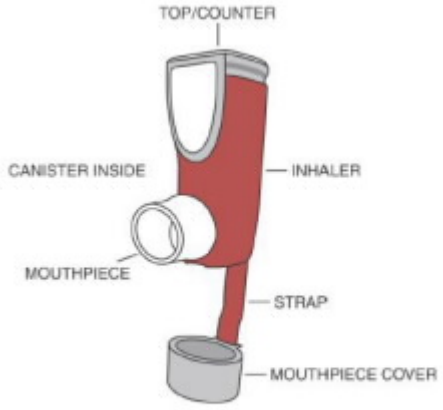
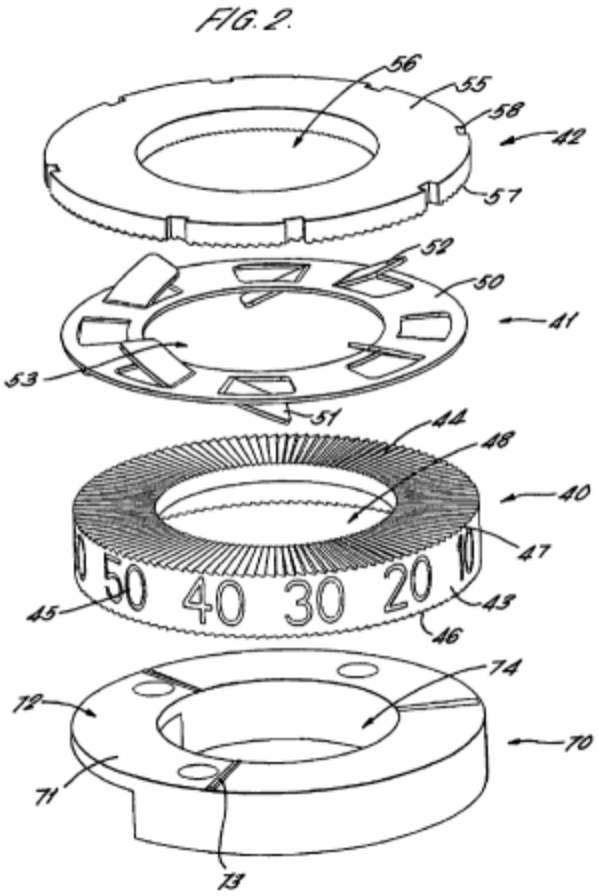


Figure 1

See, e.g., Symbicort® Prior Approval Supplement 2007, Medication Guide 8, 12. Like other products incorporating dose indicators, AstraZeneca's Symbicort® failed to provide patients with the precise number of doses remaining. As a result, Symbicort® provided a highly imperfect solution to the problems recognized by the prior art. Additionally, Symbicort®'s top-mounted design increased the bulkiness of the inhaler and opportunities for accidental or intentional damage. *See, e.g.*, *supra* Section IX.A.2.

445. **Bespak.** At around the priority dates, Bespak was attempting to develop a dose indicator for use with its inhalation products. *See, e.g.*, U.S. Patent No. 7,407,066 ("Bespak '066"). Although described by Bespak as "dose counters," Bespak's product candidates appear to have consisted of dose indicators that provided highly imprecise information regarding the number of doses remaining. Thus, they failed to adequately address the problems recognized by the prior art. *See, e.g.*, *supra* Section IX.A.2.



See, e.g., Bespak '066, Fig. 2, 2:4-3:50. Notably, [redacted] Cipla chose not to select a Bespak dose counter or dose indicator.

446. **Cipla.** At around the priority dates, Vortran Medical Technology 1, Inc. ("Vortran") was attempting to develop inhalers and dose indicators; Vortran subsequently assigned to Cipla its interest in those technologies. *See, e.g.*, U.S. Patent No. 7,600,512 ("Cipla '512"); Assignment Records for U.S. Patent No. 7,600,512. Although described by Vortran as "dose counters," the dose counting mechanisms in those devices provided highly imprecise information regarding the number of doses remaining. *See, e.g.*, *supra* Section IX.A.2.

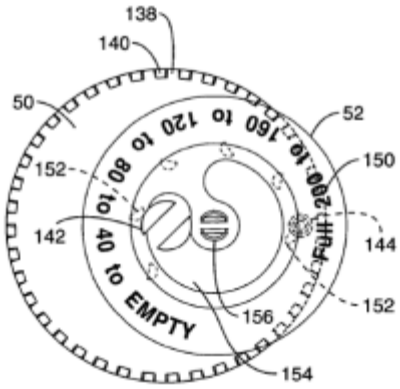


FIG. 12A

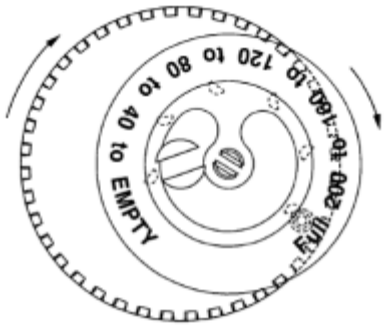


FIG. 12B

See, e.g., Cipla '512, Figs. 12A-12B, 12:53-13:12. Notably, Cipla did not use one of its own dose counters or dose indicators in its products. *See, e.g.*, CIPLA-BDI_0010839, at -840 (Container Closure System).

447. **GlaxoSmithKline.** At around the priority dates, GlaxoSmithKline received approval for several metered dose inhalation products that incorporated dose counters, including Advair® HFA, Flovent® HFA, and Ventolin® HFA. However, in each of these products, the dose counter was attached to the medicament canister. *See, e.g.*, Advair® Labeling 2009, at 41 ("Each canister is fitted with a dose counter . . ."); Flovent® Labeling 2008, CIPLA-BDI_0184100, at -123 (same); Ventolin® Labeling 2008, CIPLA-BDI_0184396, at -398 ("VENTOLIN HFA has a dose counter attached to the canister . . ."). As with other, similar approaches, attaching the dose counter to the medicament canister in those products resulted in

significantly limited their compatibility with existing medicament canisters and canister housings. *See, e.g.*, *supra* Section IX.A.2.

448. In addition to these products, GlaxoSmithKline also marketed a dry powder version of Advair®, which incorporated a dose counter. *See, e.g.*, Advair® Labeling 2008, CIPLA-BDI_0183908, at -999. However, as evidenced by GlaxoSmithKline's use of other approaches in its metered dose inhalation products, such solutions suitable for breath-actuated dry powder inhalers were generally inappropriate for metered dose inhalers because, for example, they did not need to account for variations in stroke length, which posed a significant problem in the case of metered dose inhalers. In the case of breath-actuated dry powder inhalers, the patient typically provides some additional action, which further assists in causing the mechanism to count. *See, e.g.*, '289 Patent, 1:27-2:20 ("[I]n particular, it is felt that it would be useful to provide extremely accurate dose counters for manually-operated canister-type metered dose inhalers. Unfortunately, in these inhalers, it has been found in the course of making the present invention that the stroke length of the canister is to a very large extent controlled on each dose operation by the user, and by hand. Therefore, the stroke length is highly variable and it is found to be extremely difficult to provide a highly reliable dose counter for these applications.").

449. **Nexus6.** At around the priority dates, Nexus6 and its predecessors attempted to develop electronic "reminders" for use in inhalation products, including metered dose inhalers. *See, e.g.*, U.S. Patent Publication No. 2008/0230057 ("Reminder for a Medicament Inhaler"); Assignment Records for U.S. Patent Publication No. 2008/0230057. Ultimately, in 2009 and 2014, FDA approved Nexus6's SmartTrack® and SmartTouch® devices, which were external, "clip-on" devices to be attached to existing metered dose inhalers. *See, e.g.*, SmartTrack® Approval Letter 2009, at 1; SmartTouch® Approval Letter 2014, at 1.

See, e.g., Dolan 2014. As the above image of the SmartTouch® illustrates, however, SmartTouch® and SmartTrack® were extremely bulky and susceptible to accidental or intentional damage, and as a consequence, never saw widespread use. *See, e.g.*, *supra* Section IX.A.2.

450. **Meditrack Products, Respirics. Teamm Pharmaceuticals.** At around the priority dates, Meditrack Products and Respirics/Teamm Pharmaceuticals were separately attempting to develop add-on dose counters for use with existing metered dose inhalers. *See, e.g.*, Hess 2008, at 710-11, Lewis 2008, CIPLA-BDI_0184747, at -750. Meditrack Products and Respirics/Teamm Pharmaceuticals, branded their devices as the Doser™ and the MD Turbo™, respectively. *See, e.g.*, Hess 2008, at 710-11, Lewis 2007, CIPLA-BDI_0184747, at -750.

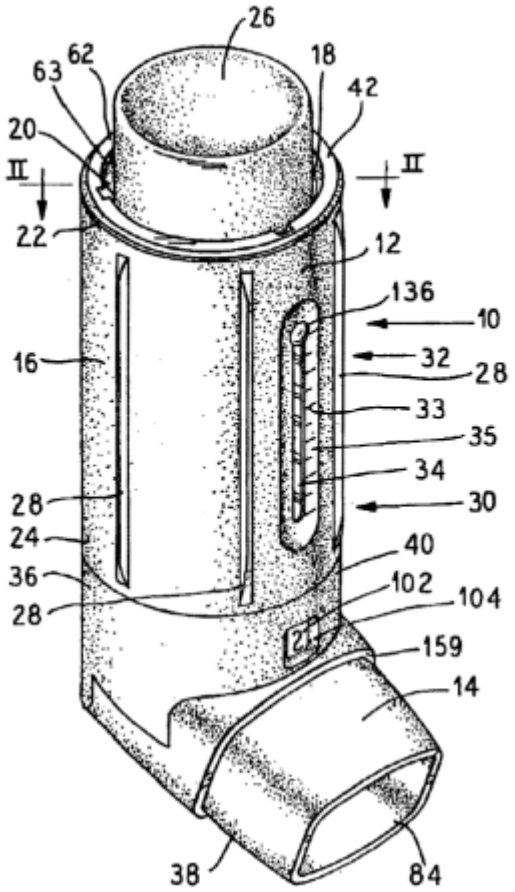
See, e.g., Hess 2008, at 710-11. As with other, similar solutions, and unlike the inventions recited in the Asserted Claims, the MD Turbo™ (left) and the Doser™ (right) were extremely bulky and in at least some circumstances, unreliable. *See, e.g.*, *supra* Section IX.A.2.

451. Indeed, commentators noted that the Doser™, MD Turbo™, and other add-on devices suffered from poor reliability, ergonomics, and compatibility. *See, e.g.*, Hess 2008, at 711 ("[T]he Doser occasionally recorded additional actuations. Over time, there was a trend toward decreasing accuracy with the Doser, which may be explained by battery decay. Also, the Doser no longer records actuations after the preset counter reaches zero, which leads to premature arrival of the counter at zero and subsequent inability to record further doses. An issue that has not been adequately addressed with these add-on dose counting devices is patient satisfaction. For example, they add to the cost of therapy and they increase the complexity of therapy because they add a device to the treatment regimen. Some of the devices, such as MD Turbo, are also not compatible with spacers and VHCs."); Williams 1999, at 1499 ("When holding th[e] Doser-MDI combination between the thumb and forefinger, the distance may be too far for some patients to actuate comfortably. This may be difficult, especially for arthritic patients, children, or other persons with small hands.").

452. **Sapphire Designs.** At around the priority dates, Sapphire Designs, was

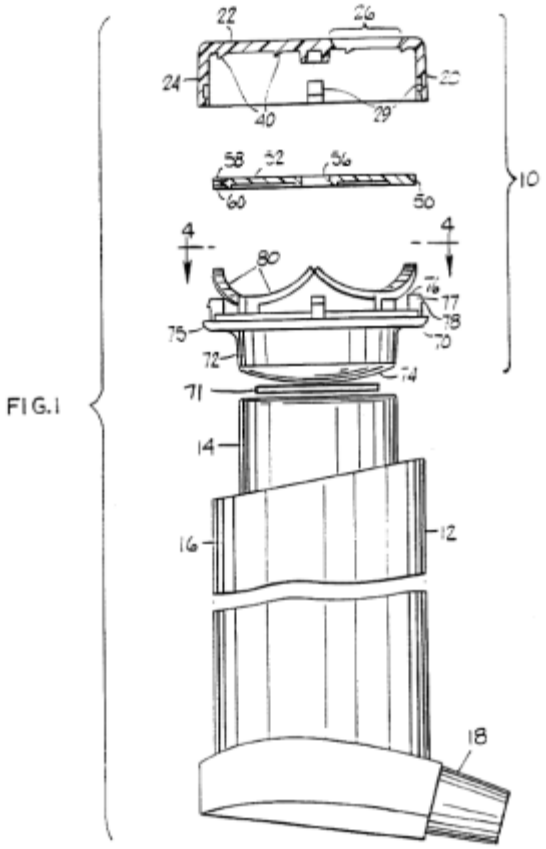
attempting to develop inhalers with "level indicators." Sapphire Designs' level indicators extended along the canister housing and indicated the level of medicine remaining. *See, e.g.*, U.S. Patent No. 6,615,827, Abstract, Figs. 1-15, 22-54; 3:6-24:38 ("Sapphire '827").

FIG. 1



See, e.g., Sapphire '827, Fig. 1, 16:18-20; 7:17-8:11. Based on Sapphire Designs' publications, it is unclear whether at around the priority dates, Sapphire Designs ever succeeded in creating a product candidate that included a dose counter (as opposed to a dose indicator); and in any event, because of their side-mounted design, Sapphire Designs' product candidates were bulky and suffered from poor compatibility with existing medicament canisters and canister housings. *See, e.g.*, *supra* Section IX.A.2.

453. **Senetics.** At around the priority dates, Senetics was attempting to develop dose indicators for use with inhalation drug products. *See, e.g.*, U.S. Patent No. 5,718,355 ("Senetics '355"). Senetics's product candidates attached to the top of the medicament canister, which were activated by the patient's pressing down on the medicament canister. *See, e.g.*, Senetics '355, Abstract, Figs. 1-16, 6:10-30:36.



See, e.g., Senetics '355, Fig. 1; 7:35-62. Accordingly, Senetics's product candidates suffered from multiple problems. As dose indicators, Senetics's product candidates did not inform patients of the precise number of doses remaining; and because they attached to the top of the medicament canister, were bulky and susceptible to accidental or intentional damage. *See, e.g.*, *supra* Section IX.A.2.

454. **Trudell Medical.** In 2008, FDA approved Nycomed's Alvesco®, which

incorporates Trudell Medical's AeroCount® dose indicator. *See, e.g.*, Alvesco® Labeling 2008, at 11. DESCRIPTION ("ALVESCO 80 mcg Inhalation Aerosol and ALVESCO 160 mcg Inhalation Aerosol are pressurized, metered-dose aerosol units fitted with a dose indicator"). Like other dose indicators, Trudell Medical's AeroCount® failed to provide patients with the number of doses remaining. Moreover, because Trudell Medical's AeroCount® was attached to the top of the medicament canister, Trudell Medical's attempted solution resulted in additional bulkiness and increased opportunities for accidental or intentional damage. *See, e.g.*, *supra* Section IX.A.2.

455. **Cohero/Newtec.** It bears mention that even years after the priority dates, pharmaceutical companies continued to struggle to develop inhalers and dose counters or dose counters having the properties of the claimed inventions. Thus, by way of example, both Cohero Health, Inc. ("Cohero"), U.S. Patent No. 10,091,555, and Newtec Pro Manufacturing Pvt. Ltd. ("Newtec"), U.S. Patent No. 10,765,819, attempted to develop electronic dose counters and front-facing dose indicators, respectively. However, like their predecessors, Cohero's and Newtec's product candidates suffered from the flaws of those approaches, including bulkiness, unreliability, and poor compatibility with medicament canisters and canister housings.

456. In my opinion, each of these failures, alone and in combination with one or more other failures, provides further evidence that the inventions recited in the Asserted Claims would not have been obvious.

C. Industry Acceptance

457. In my opinion, the inhalation device industry's acceptance of the inventions recited in the Asserted Claims, as embodied by Qvar® HFA with dose counter and ProAir® HFA with dose counter, provides further evidence that those inventions would not have been obvious. Both Qvar® HFA with dose counter and ProAir HFA® with dose counter have

achieved FDA approval for use in treating the diseases for which they are indicated. *See, e.g.*, Qvar® Supplemental Approval Letter 2014, TEVADOC-00000042; ProAir® HFA Labeling 2012, TEVADOC-00000016 As an active industry consultant for that industry, I routinely discuss inhalation devices with other industry participants, in both commercial and academic settings. In my experience, at the time of their approvals, industry participants considered Qvar® HFA with dose counter and ProAir® HFA with dose counter to be leading products for their respective indications. Indeed, in my conversations with pharmaceutical companies, I frequently refer to Qvar® HFA with dose counter as a leading inhalation product that incorporates a dose counter. Because my discussions focused on the design of these products, it was clear to me that the acceptance directed to towards those products was based on the inventions recited in the Asserted Claims. The inhalation device industry's acceptance of Qvar® HFA with dose counter and ProAir® HFA with dose counter further evidences that the claimed inventions would not have been obvious.

D. Praise

458. In my opinion, the inhalation device industry's praise for the inventions recited in the Asserted Claims, as embodied by Qvar® HFA with dose counter and ProAir® HFA with dose counter, provides further evidence that those inventions would not have been obvious. On multiple occasions, I have been involved in conversations in which other industry participants have praised the designs of Qvar® HFA with dose counter and ProAir® HFA with dose counter, for their functionality, accuracy (including, with respect to under- and over-counting), reliability, maintainability (including their ability to be cleaned), robustness, manufacturability, minimal impact on device performance, and human factors (including their aesthetics, ergonomics, and other human factors). Among other things, those individuals praised Qvar® HFA with dose counter and ProAir® HFA with dose counter for providing integrated, dose-counting solutions

that appeal to patients because of their non-bulky designs.

459. Additionally, numerous physicians and researchers have praised Qvar® HFA with dose counter and ProAir HFA® with dose counter for their accuracy, reliability, and performance—including, their ability to significantly reduce hospitalizations and emergency room visits. *See, e.g.*, Given 2012, TEVADOC-00000010 ("ProAir HFA MDI with the new integrated dose counter functioned reliably and accurately in the clinical setting."); Chipps 2017, TEVADOC-00000008 ("In patients with asthma and/or COPD, albuterol inhalation aerosol (ProAir HFA) with dose counter, compared with the same product without dose counter, had significantly lower healthcare resource use including all-cause and respiratory-related inpatient ED visits, higher refill rates, and fewer exacerbations."); Kerwin 2017, at 1 ("In a real-world setting, asthma patients using ProAir HFA with [dose counter] experienced significantly fewer hospitalizations and [emergency department] visits compared with patients using ProAir HFA without [dose counter.]").

460. [redacted]

[redacted]

E. Copying

461. In my opinion, Defendants' copying of the inventions recited in the Asserted Claims, as embodied in Qvar® HFA with dose counter, provides further evidence that those inventions would not have been obvious. As explained above in my analysis of prior art devices, Defendants had the opportunity to select a number of different inhaler and dose counter designs, including a number of different combinations of components, features, and configurations. *See, e.g.*, *supra* Sections IX.A.2, IX.B. Nevertheless, despite the availability of these design options, Defendants chose to select the same components, features, and configurations as those recited in the Asserted Claims or their equivalents. Indeed, Cipla chose to add a dose counter to its product based on Teva's announcement that it had added a dose counter to Qvar® HFA. *See, e.g.*, Rote Dep. Tr. 101:11-104:3; Rote Dep. Ex. 10, CIPLA-BDI_0788345; Rote Dep. Ex. 11, CIPLA-BDI_0876040 (Cipla E-Mails re. Teva Qvar® with Dose Counter Press Release). That further evidences that the claimed inventions would not have been obvious.

Dated: April 29, 2022

Dr. David Lewis. Ph.D.

X. Exhibit B

Axial Displacement of Medicament Canister With/Without Inner Wall Canister Support Formations

A. Part 1: Measure Height of Medicament Canister and Valve Assembly.

1. Experimental Setup

- Equipment: Texture Analyser TA.HDi, with 5 kg Load Cell
- Calibration: 2 kg certified calibration weight
- Trigger Force: 0.1 N
- Test Speed: 1 mm/s
- Probe: 2 mm stainless steel blunt probe.
- Distance: Relative to Base (mm)

2. Methodology

- The probe is brought down onto baseplate that the medicament canister/valve assembly is standing on; the position of the probe is recorded (mm).
- The probe is brought down onto the top of the valve stem until a 0.1 N trigger force is registered; the position of the probe is recorded (mm).
- The relative position of the valve stem is calculated to give the height of the canister/valve assembly.
- Repeat 5 measurements.

3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

- Mean ± Standard Deviation: 61.58 ± 0.01 mm (n=5)

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

- Mean ± Standard Deviation: 61.46 ± 0.01 mm (n=5)

B. Part 2: Measure Axial Displacement of Medicament Canister With/Without Inner Wall Canister Support Formations.

1. Experimental Setup

- Equipment: Texture Analyser TA.HDi, with 5 kg Load Cell
- Calibration: 2 kg certified calibration weight
- Trigger Force: 0.1 N
- Test Speed: 1mm/s
- Probe: 2mm stainless steel blunt probe
- Distance: Relative to trigger (mm)

2. Methodology

- The metered dose inhaler is fixed horizontally to the base plate
- The canister end is held in tension to the near surface of the actuator housing.
- The probe is brought centrally down to the base of the canister until a trigger force of 0.1 N is registered.
- The probe continues to push the canister to the far side of the actuator housing until a force of 10 N is registered.
- The distance of the probes movement from the trigger point is recorded.
- The measurement is repeated 5 times.
- The orientation of the metered dose inhaler is evaluated left to right, right to left and front to back.

3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

		Mean ± Standard Deviation
Canister/Valve Assembly Height (mm), (n = 5)		61.58 ± 0.01
Maximum Side-to-Side Movement (mm)	**As Supplied** (n = 10)	1.93 ± 0.05
	Ribs Removed (n = 10)	3.4 ± 0.2
Maximum Front-to-Back Movement (mm)	**As Supplied** (n = 5)	2.15 ± 0.01
	Ribs Removed (n = 5)	3.11 ± 0.02
Maximum Angle to Normal (°)	**As Supplied** (n = 15)	0.9 ± 0.1
	Ribs Removed (n = 15)	1.5 ± 0.1

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

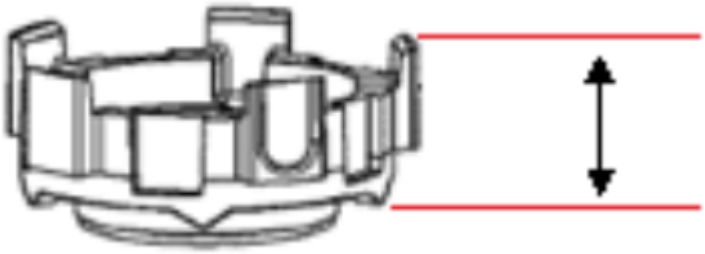
		Mean ± Standard Deviation
Canister/Valve Assembly Height (mm), (n = 5)		61.46 ± 0.01
Maximum Side-to-Side Movement (mm)	**As Supplied** (n = 10)	2.00 ± 0.02
	Ribs Removed (n = 10)	3.01 ± 0.01
Maximum Front-to-Back Movement (mm)	**As Supplied** (n = 5)	2.37 ± 0.06
	Ribs Removed (n = 5)	3.12 ± 0.01
Maximum Angle to Normal (°)	**As Supplied** (n = 15)	1.0 ± 0.1
	Ribs Removed (n = 15)	1.4 ± 0.1

XI. Exhibit C

Force and Displacement of Triangular Protrusions Relative to Datum Plane

A. Part 1: Measure Depth of Lowest Point of Triangular Protrusions Relative to Top Face of Castellations

Measure the relative position of the lowest point of the triangular protrusions on Cipla's "indexer" to the top face of the indexer castellations.



1. Experimental Setup

- Equipment: Callipers, Mitutoyo CD-6"CSX

2. Methodology

- Measure the distance between the lowest point of the triangular protrusions on what indexer and the top face of the indexer castellations, record in mm.
- Measure for each of the five triangular protrusions three separate dose counters.

3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Relative Distance of Triangular Protrusions to Top Face of Castellations (mm)		
Dose Counter 1	**Dose Counter 2**	**Dose Counter 3**
5.67	5.60	5.64
5.68	5.62	5.64
5.66	5.64	5.63
5.68	5.63	5.64
5.65	5.63	5.60

Mean ± Standard Deviation: 5.64 ± 0.02 mm (n = 15)

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Relative Distance of Triangular Protrusions to Top Face of Castellations (mm)
Dose Counter 1
5.62
5.61
5.63
5.62
5.58

Mean ± Standard Deviation: 5.61 ± 0.02 mm (n = 5)

B. Part 2: Create Force-Displacement Plot for Castellation Displacement (No Stem Resistance)

Measure the force versus displacement for a dose counter during metered dose inhaler actuation. The stem is removed from the metered dose inhaler so that no interaction with seating block occurs. i.e., forces and displacements measured are that solely of the dose counter.

1. Experimental Setup

- Equipment: Texture Analyser TA.HDi, with 5 kg Load Cell
- Calibration: 2 kg certified calibration weight
- Trigger Force: 0.2 N
- Test Speed: 1 mm/s
- Distance: Relative to trigger (mm)
- Probe: 6 mm stainless-steel blunt probe
- Compression: Measure Force

2. Methodology

- Each data point is representing the mean ± standard deviation from five measurements.

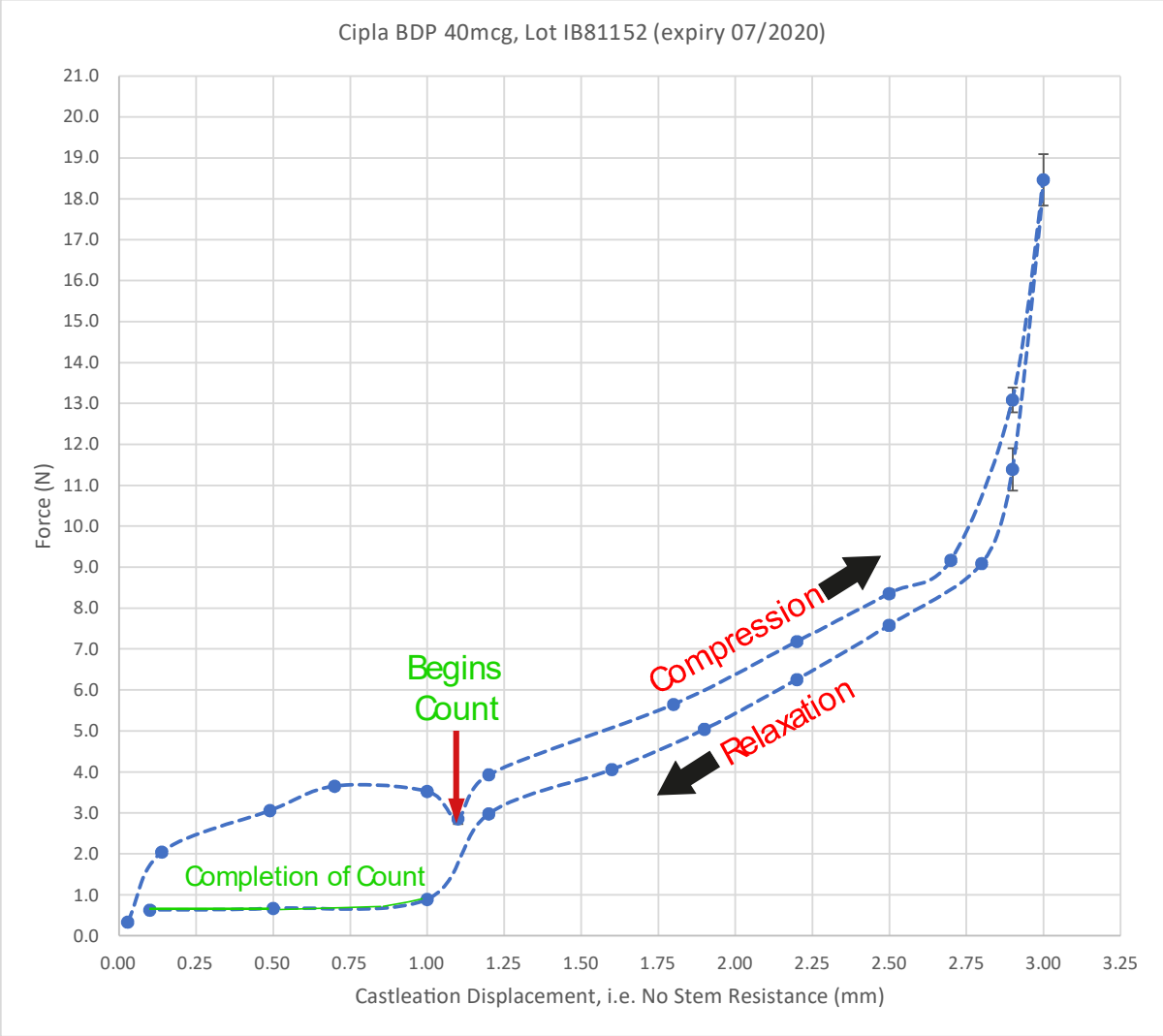
3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Replicates, n = 5

Distance (mm)		Force (N)		Dose Counts
Mean	Standard Deviation	Mean	Standard Deviation	
0.028	0.001	0.330	0.025	no
0.139	0.001	2.042	0.013	no
0.490	0.003	3.052	0.008	no
0.700	0.000	3.648	0.004	no
1.000	0.000	3.520	0.019	no
1.100	0.000	2.854	0.128	yes
1.200	0.000	3.930	0.035	yes
1.800	0.000	5.648	0.047	yes
2.200	0.000	7.182	0.024	yes
2.500	0.000	8.362	0.094	yes
2.700	0.000	9.174	0.087	yes
2.900	0.000	13.092	0.300	yes
3.000	0.000	18.466	0.625	yes
2.900	0.000	11.390	0.520	yes
2.800	0.000	9.094	0.065	yes
2.500	0.000	7.584	0.082	yes
2.200	0.000	6.256	0.077	yes
1.900	0.000	5.038	0.061	yes
1.600	0.000	4.058	0.036	yes
1.200	0.000	2.972	0.082	yes
1.000	0.000	0.882	0.029	yes
0.500	0.000	0.662	0.016	Final Movement
0.100	0.000	0.624	0.018	Final Movement

Maximum Castellation Displacement: 3.000 ± 0.000 mm

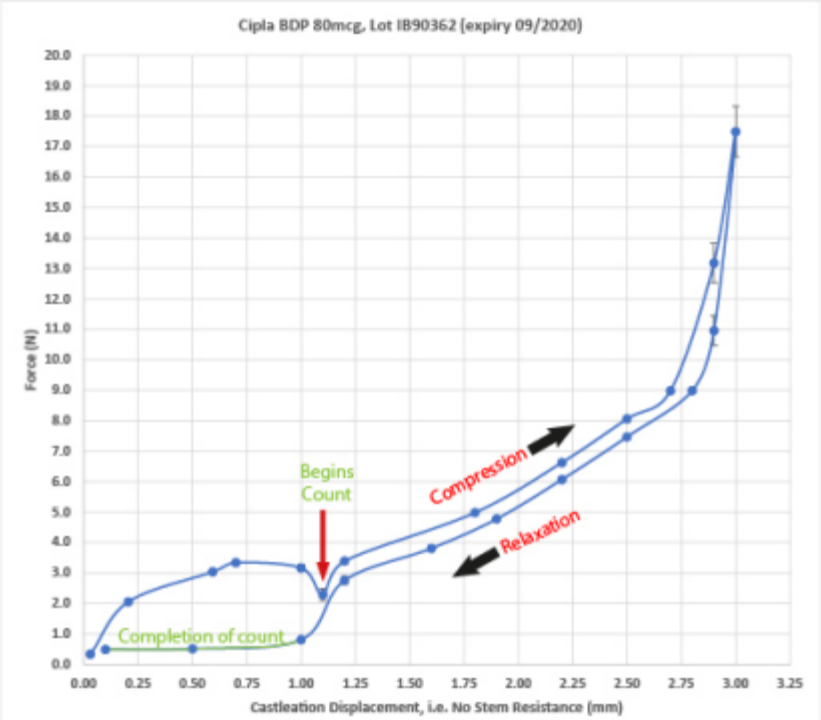

Cipla BDP 40mcg, Lot IB81152 (expiry 07/2020)
Force (N)
21.0
20.0
19.0
18.0
17.0
16.0
15.0
14.0
13.0
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0.00
0.25
0.50
0.75
1.00
1.25
1.50
1.75
2.00
2.25
2.50
2.75
3.00
3.25
Castleation Displacement, i.e. No Stem Resistance (mm)
Begins Count
Completion of Count
Compression
Relaxation

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Replicates, n = 5

Distance (mm)		Force (N)		Dose Counts
Mean	Standard Deviation	Mean	Standard Deviation	
0.030	0.001	0.338	0.029	no
0.205	0.007	2.058	0.011	no
0.593	0.002	3.040	0.007	no
0.700	0.000	3.342	0.008	no
1.000	0.000	3.170	0.107	no
1.100	0.000	2.292	0.195	yes
1.200	0.000	3.390	0.068	yes
1.800	0.000	4.984	0.047	yes
2.200	0.000	6.628	0.041	yes
2.500	0.000	8.062	0.080	yes
2.700	0.000	8.988	0.048	yes
2.900	0.000	13.180	0.651	yes
3.000	0.000	17.490	0.830	yes
2.900	0.000	10.960	0.487	yes
2.800	0.000	8.994	0.034	yes
2.500	0.000	7.474	0.034	yes
2.200	0.000	6.070	0.037	yes
1.900	0.000	4.780	0.029	yes
1.600	0.000	3.814	0.023	yes
1.200	0.000	2.762	0.130	yes
1.000	0.000	0.814	0.029	yes
0.500	0.000	0.516	0.021	Final Movement
0.100	0.000	0.494	0.011	Final Movement

Maximum Castellation Displacement: 3.000 ± 0.000 mm


Cipla BDP 80mcg, Lot IB90362 (expiry 09/2020)
Force (N)
Castleation Displacement, i.e. No Stem Resistance (mm)
Begins Count
Completion of count
Compression
Relaxation

C. Part 3: Create Force-Displacement Plot for Metered Dose Inhaler Displacement

Measure the force versus displacement for a metered dose inhaler during metered dose inhaler actuation.

1. Experimental Setup

- Equipment: Texture Analyser TA.HDi, with 5 kg Load Cell
- Calibration: 2 kg certified calibration weight
- Trigger Force: 0.2 N
- Test Speed: 1 mm/s
- Distance: Relative to trigger (mm)
- Probe: 6 mm stainless-steel blunt probe
- Compression: Measure Force

2. Methodology

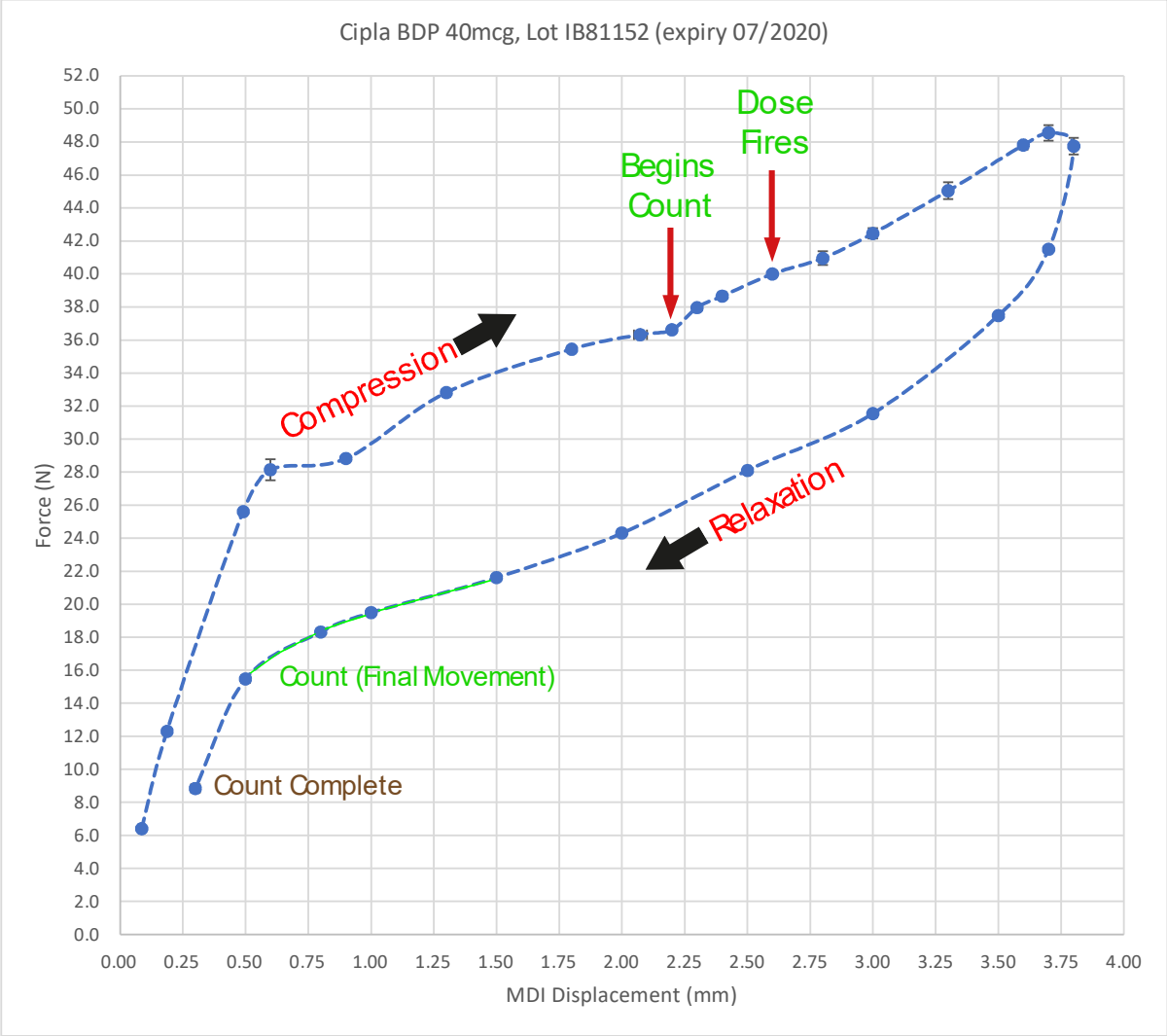
- Each data point is representing the mean ± standard deviation from five measurements.

3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Replicates, n = 5

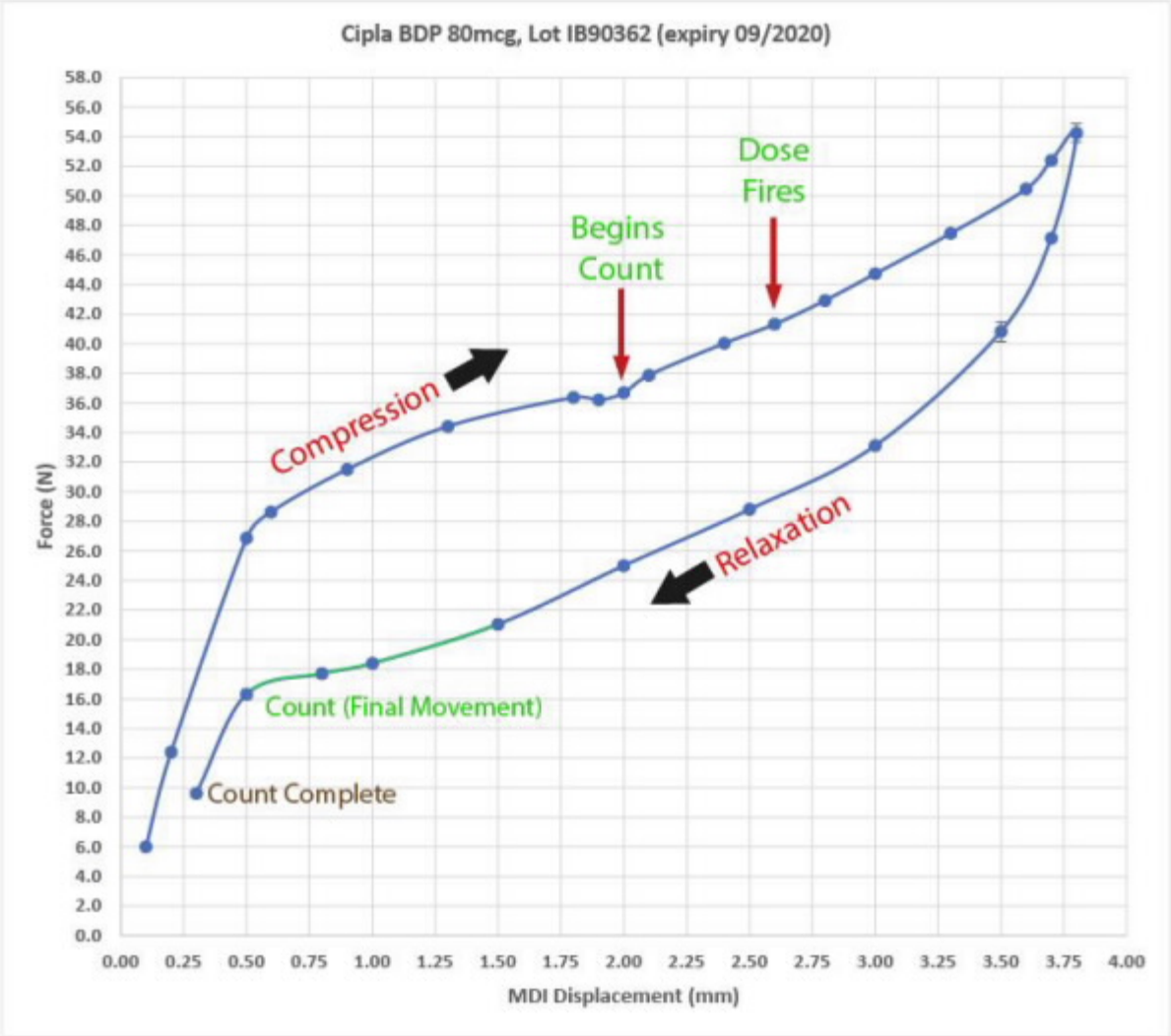
Distance (mm)		Force (N)		Dose Counts	Dose Fired
Mean	Standard Deviation	Mean	Standard Deviation		
0.086	0.001	6.388	0.036	no	no
0.188	0.001	12.292	0.068	no	no
0.491	0.001	25.620	0.069	no	no
0.599	0.001	28.144	0.642	no	no
0.900	0.000	28.822	0.128	no	no
1.300	0.000	32.822	0.052	no	no
1.800	0.000	35.452	0.040	no	no
2.073	0.025	36.326	0.143	no	no
2.199	0.001	36.618	0.105	Begins Count	no
2.300	0.000	37.970	0.022	No Movement	no
2.400	0.000	38.662	0.210	No Movement	no
2.600	0.000	40.008	0.191	No Movement	yes
2.800	0.000	40.958	0.417	No Movement	-
3.000	0.000	42.460	0.314	No Movement	-
3.300	0.000	45.042	0.516	No Movement	-
3.600	0.000	47.814	0.258	No Movement	-
3.700	0.000	48.554	0.474	No Movement	-
3.800	0.000	47.742	0.506	No Movement	-
3.700	0.000	41.502	0.085	No Movement	-
3.500	0.000	37.488	0.179	No Movement	-
3.000	0.000	31.554	0.182	No Movement	-
2.500	0.000	28.106	0.092	No Movement	-
2.000	0.000	24.312	0.130	No Movement	-
1.500	0.000	21.612	0.167	Final Movement	-
1.000	0.000	19.492	0.179	Final Movement	-
0.800	0.000	18.324	0.135	Final Movement	-
0.500	0.000	15.458	0.230	Final Movement	-
0.300	0.000	8.830	0.248	Count Complete	-


Cipla BDP 40mcg, Lot IB81152 (expiry 07/2020)
Force (N)
MDI Displacement (mm)
Dose Fires
Begins Count
Compression
Relaxation
Count (Final Movement)
Count Complete

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Replicates, n = 5

Distance (mm)		Force (N)		Dose Counts	Dose Fired
Mean	Standard Deviation	Mean	Standard Deviation		
0.100	0.000	6.012	0.083	no	no
0.200	0.000	12.398	0.101	no	no
0.500	0.000	26.864	0.042	no	no
0.597	0.000	28.624	0.225	no	no
0.900	0.000	31.508	0.096	no	no
1.300	0.000	34.418	0.026	no	no
1.800	0.000	36.370	0.032	no	no
1.900	0.000	36.200	0.019	no	no
2.000	0.000	36.684	0.133	Begins Count	no
2.100	0.000	37.880	0.019	No Movement	no
2.400	0.000	40.032	0.073	No Movement	no
2.600	0.000	41.322	0.267	No Movement	yes
2.800	0.000	42.922	0.083	No Movement	yes
3.000	0.000	44.734	0.087	No Movement	yes
3.300	0.000	47.462	0.199	No Movement	yes
3.600	0.000	50.466	0.157	No Movement	yes
3.700	0.000	52.388	0.147	No Movement	yes
3.800	0.000	54.246	0.625	No Movement	yes
3.700	0.000	47.132	0.118	No Movement	yes
3.500	0.000	40.828	0.657	No Movement	yes
3.000	0.000	33.114	0.200	No Movement	yes
2.500	0.000	28.804	0.072	No Movement	yes
2.000	0.000	25.004	0.236	No Movement	yes
1.500	0.000	21.044	0.139	Final Movement	yes
1.000	0.000	18.402	0.158	Final Movement	yes
0.800	0.000	17.704	0.273	Final Movement	yes
0.500	0.000	16.314	0.312	Final Movement	yes
0.300	0.000	9.614	0.240	Count Complete	yes


Cipla BDP 80mcg, Lot IB90362 (expiry 09/2020)
Force (N)
MDI Displacement (mm)
Dose Fires
Begins Count
Compression
Relaxation
Count (Final Movement)
Count Complete

D. Part 4: Measure Position of Datum Plane Relative to Top Face of Castellations

Measure the relative position of the datum plane to the top face of Cipla's "indexer" castellations when metered dose inhaler is at rest.

1. Experimental Setup

- Equipment: Texture Analyser TA.HDi, with 5 kg Load Cell
- Calibration: 2 kg certified calibration weight
- Trigger Force: 0.2 N
- Test Speed: 1 mm/s
- Distance: Relative to Base (mm)
- Probe: 3 mm stainless-steel blunt probe

2. Methodology

- The probe is brought down onto the first datum; the position of the probe is recorded (mm).
- The probe is brought down onto the top edge of indexer castellation; the position of the probe is recorded (mm).
- Repeat for 3 separate indexer castellations on each metered dose inhaler tested (n = 5).
- Two MDIs, total measurements = 30. One MDI, total measurements = 15.
- Touch force to top of castellation = 0.22 ± 0.02 N.

3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

- Mean ± Standard Deviation: -5.48 ± 0.03 mm (n = 30)

Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

- Mean ± Standard Deviation: -5.45 ± 0.12 mm (n = 15)

E. Part 5: Measure Force Versus Displacement of Leaf Spring Removed From Dose Counter

Measure the force versus displacement of a leaf spring removed from a dose counter.

1. Experimental Setup

- Equipment: Texture Analyser TA.HDi, with 5 kg Load Cell
- Calibration: 2 kg certified calibration weight
- Trigger Force: 0.2 N
- Test Speed: 2 mm/s
- Distance: Relative to trigger
- Probe: Between flat surfaces

2. Methodology

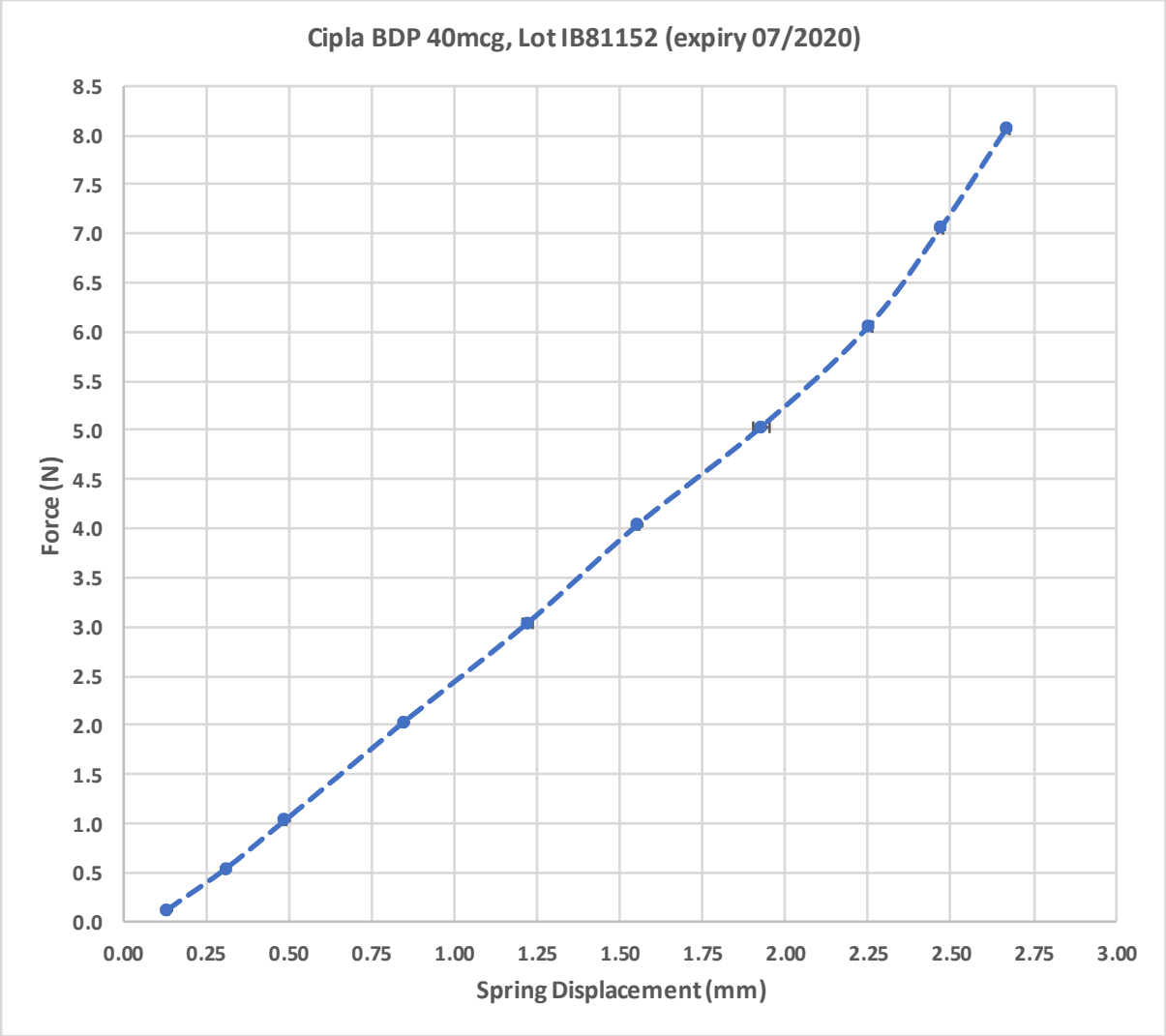
- Each data point represents the mean ± standard deviation from five measurements.

3. Results

Test Sample: Cipla's ANDA Product, 40 mcg, Lot IB81152 (exp. 07/2020)

Mean ± Standard Deviation (n=5)

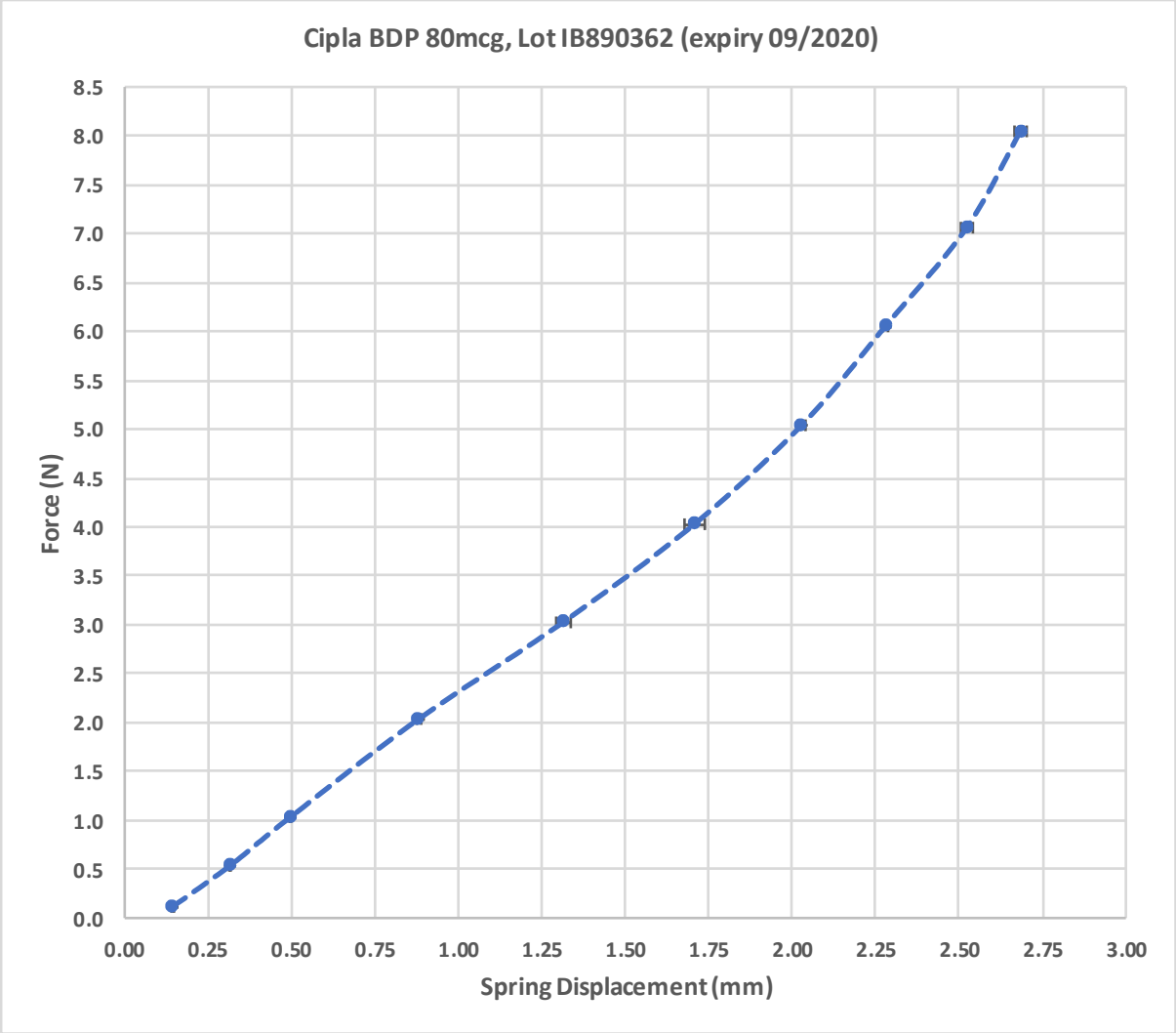
Distance (mm)	Force (N)
0.132 ± 0.004	0.118 ± 0.004
0.307 ± 0.003	0.534 ± 0.005
0.488 ± 0.004	1.030 ± 0.007
0.847 ± 0.003	2.028 ± 0.004
1.221 ± 0.015	3.036 ± 0.009
1.554 ± 0.004	4.036 ± 0.009
1.927 ± 0.025	5.030 ± 0.007
2.250 ± 0.012	6.050 ± 0.007
2.468 ± 0.008	7.048 ± 0.008
2.667 ± 0.010	8.062 ± 0.013



Test Sample: Cipla's ANDA Product 80 mcg, Lot IB90362 (exp. 09/2020)

Mean ± Standard Deviation (n=5)

Distance (mm)	Force (N)
0.144 ± 0.004	0.112 ± 0.004
0.315 ± 0.002	0.532 ± 0.004
0.496 ± 0.002	1.030 ± 0.000
0.881 ± 0.007	2.034 ± 0.005
1.315 ± 0.022	3.024 ± 0.005
1.707 ± 0.030	4.028 ± 0.004
2.029 ± 0.011	5.040 ± 0.000
2.280 ± 0.008	6.052 ± 0.011
2.523 ± 0.018	7.062 ± 0.015
2.684 ± 0.019	8.046 ± 0.009


Cipla BDP 80mcg, Lot IB890362 (expiry 09/2020)
Force (N)
8.5
8.0
7.5
7.0
6.5
6.0
5.5
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0.00
0.25
0.50
0.75
1.00
1.25
1.50
1.75
2.00
2.25
2.50
2.75
3.00
Spring Displacement (mm)

XII. Exhibit D

In my opinion, Qvar® HFA with dose counter and ProAir® HFA with dose counter satisfy every limitation of the Asserted Claims. Thus, in my opinion, Qvar® HFA with dose counter and ProAir® HFA with dose counter are embodiments of each of the Asserted Claims. The following charts set forth my analysis in greater detail. Claims highlighted in grey are not asserted, but contain limitations incorporated into the Asserted Claims from which they depend.

In performing this analysis, I reviewed relevant portions of the Qvar® HFA and ProAir® HFA New Drug Applications, Design History Files, Engineering Qualification Reports, and other materials. *See, e.g.*, TEVAQVAR-00008706 (Qvar® HFA Container Closure System); TEVAQVAR-00010727 (Qvar® HFA Labeling); TEVAQVAR-00765383 (Qvar® HFA Design History File); TEVAQVAR-00765418 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00052614 (ProAir® HFA Container Closure System); TEVAQVAR-00066638 (ProAir® HFA Labeling); TEVAQVAR-00764323 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report). I further reviewed the deposition transcripts of Mr. Declan Walsh and Mr. Jeffrey Karg, the two named inventors deposed in this litigation.[7]

A. U.S. Patent No. 9,463,289 ('289 Patent)

No.	Claim Limitations(s)	Qvar® HFA	ProAir® HFA
1	An inhaler for metered dose inhalation, the inhaler comprising:	Qvar® HFA is an inhaler for metered dose inhalation. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling);	ProAir® HFA is an inhaler for metered dose inhalation. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir HFA® Labeling);

[7] I note that Defendants do not contend that Qvar® HFA with dose counter and ProAir® HFA with dose counter are embodiments of the claimed inventions, and that one of the Defendants has cited the ProAir® HFA Labeling as a basis for asserting that the claimed inventions would have been obvious. *See* Aurobindo Invalidity Contentions; Cipla Invalidity Contentions.

		TEVAQVAR-00008706 at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085, TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).
	a main body having a canister housing,	Qvar® HFA's inhaler comprises a main body having a canister housing. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706 at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA's inhaler comprises a main body having a canister housing. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).
	a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and	Qvar® HFA's inhaler comprises a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706 at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383,	ProAir® HFA's inhaler comprises a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323,

		at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).
	a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,	Qvar® HFA's inhaler comprises a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764088; TEVAQVAR-00764090 (Qvar® HFA Design Drawings). The '289 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 5:26-34, 7:20-25, 12:13-16:37, Figs. 1, 6, 8, 10.	ProAir® HFA's inhaler comprises a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539312-13, TEVQVAR-00539316-17 (Design Drawings). The '289 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 5:26-34, 7:20-25, 12:13-16:37, Figs. 1, 6, 8, 10.
	wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,	Qvar® HFA is an inhaler wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling);	ProAir® HFA is an inhaler wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling);

	and	TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings). The '289 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7.	TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings). The '289 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7.
	wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,	Qvar® HFA is an inhaler wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, -765 393-395 (Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, -764 348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

		[redacted]	
		The '289 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 6:50-58, Figs. 7C, 7D.	ProAir® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 6:50-58, Figs. 7C, 7D.
	the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.	Qvar® HFA is an inhaler wherein the inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383,	ProAir® HFA is an inhaler wherein the inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323,

		at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; [redacted] The '289 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '289 Patent, 6:34-7:19, Figs. 1-3, 7.	at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-0053931213 (ProAir HFA® Design Drawings). Patent, 6:34-7:19, Figs. 1-3, 7.
2	The inhaler as	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.

	claimed in claim 1		
	wherein the medicament canister is movable relative to the dose counter.	Qvar® HFA is an inhaler wherein the medicament canister is movable relative to the dose counter. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein the medicament canister is movable relative to the dose counter. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).
4	The inhaler as claimed in claim 1,	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	Wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.	Qvar® HFA is an inhaler wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report);	ProAir® HFA is an inhaler wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design

		TEVAQVAR-00764085; TEVAQVAR-00764090	Drawings).
		[redacted]	
5	The inhaler as claimed in claim 4,		
	wherein the support rail includes a step formed thereon	Qvar® HFA is an inhaler wherein the support rail includes a step formed thereon. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein the support rail includes a step formed thereon. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

		[redacted]	
6	The inhaler as claimed in claim 4	*See* '289 Patent, Claim 4.	*See* '289 Patent, Claim 4.
	further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.	Qvar® HFA is an inhaler further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, -765 393-395 (Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

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7	The inhaler as claimed in claim 6,	*See* '289 Patent, Claim 6.	*See* '289 Patent, Claim 6.
	wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.	Qvar® HFA is an inhaler wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

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B. U.S. Patent No. 9,808,587 ('587 Patent)

No.	Claim Limitation(s)	Qvar® HFA	ProAir® HFA
1	An inhaler for metered dose inhalation, the inhaler comprising:	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	a main body having a canister housing,	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.

	of the inner wall,		
	wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	wherein the first inner wall canister support formation, the wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.	Qvar® HFA is an inhaler wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protected against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

		[redacted]	
		The '587 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.	ProAir® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.
2	The inhaler as claimed in claim 1	*See* '587 Patent, Claim 1.	*See* '587 Patent, Claim 1.
	wherein the medicament canister is movable relative to the dose counter.	Qvar® HFA's inhaler comprises a medicament canister, which is moveable relative to the dose counter. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar®	ProAir® HFA's inhaler comprises a medicament canister, which is moveable relative to the dose counter. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir

		HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-0053931213 (ProAir HFA® Design Drawings).
3	The inhaler as claimed in claim 1	*See* '587 Patent, Claim 1.	*See* '587 Patent, Claim 1.
	further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.	Qvar® HFA's inhaler comprises an aperture formed in the inner wall through which the portion of the actuation member extends. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706 at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA's inhaler comprises an aperture formed in the inner wall through which the portion of the actuation member extends. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-0053931213 (ProAir HFA® Design Drawings).
4	The inhaler as claimed in claim 1,	*See* '587 Patent, Claim 1.	*See* '587 Patent, Claim 1.
	wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.	Qvar® HFA is an inhaler wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706	ProAir® HFA is an inhaler wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614,

		at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings). The '587 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.	at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings). The '587 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.
5	The inhaler as claimed in claim 4,	*See* '587 Patent, Claim 1.	*See* '587 Patent, Claim 1.
	wherein the support rail includes a step formed thereon	Qvar® HFA is an inhaler wherein the support rail includes a step formed thereon. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090	ProAir® HFA is an inhaler wherein the support rail includes a step formed thereon. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

		[redacted]	
6	The inhaler as claimed in claim 4	*See* '587 Patent, Claim 4.	*See* '587 Patent, Claim 4.
	further comprising a plurality of support rails each of which extends longitudinally along the inside surface of the main body.	Qvar® HFA is an inhaler further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, -765 393-395 (Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-0053931213 (ProAir HFA® Design Drawings).

		[redacted]	
7	The inhaler as claimed in claim 6,	*See* '587 Patent, Claim 6.	*See* '587 Patent, Claim 6.
	wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other	Qvar® HFA is an inhaler wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

		[redacted]	
8	The inhaler as claimed in claim 4,		
	wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.	Qvar® HFA is an inhaler wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

		[redacted]	
13	An inhaler for metered dose inhalation, the inhaler comprising:	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	a main body having a canister housing,	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	a medicament canister retained in the canister housing and movable relative thereto,	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
	wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.

	of the inner wall,		
	wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and	*See* '289 Patent, Claim 3.	*See* '289 Patent, Claim 3.
	wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.	*See* '289 Patent, Claim 1.	*See* '289 Patent, Claim 1.
21	The inhaler as claimed in claim 13,	*See* '587 Patent, Claim 13.	*See* '587 Patent, Claim 13.
	wherein the first inner wall canister support formation, the aperture, and a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with a longitudinal axis X which passes through the center of the central outlet port.	Qvar® HFA is an inhaler wherein the first inner wall canister support formation, the aperture, and the central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with the longitudinal axis X which passes through the center of the central outlet port. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168	ProAir® HFA is an inhaler wherein the first inner wall canister support formation, the aperture, and the central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, all lie in a common plane coincident with the longitudinal axis X which passes through the center of the central outlet port. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426

		(Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design	(ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-0053931213 (ProAir HFA® Design Drawings).
		[redacted]	
		The '587 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.	limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.
22	The inhaler as claimed in claim 21	*See* '587 Patent, Claim 21.	*See* '587 Patent, Claim 21.
	further comprising a second inner wall	Qvar® HFA is an inhaler wherein a second inner wall	ProAir® HFA is an inhaler wherein a second inner wall

	canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X.	canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00007168 (Qvar® HFA Drop Test); TEVAQVAR-00765418, at -419-25, -586-45 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764085; TEVAQVAR-00764090 (Qvar® HFA Design Drawings).	canister support formation and wherein the second inner wall canister support formation, the first inner wall canister support formation, the aperture, and the central outlet port lie in a common plane coincident with longitudinal axis X. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539312-13 (ProAir HFA® Design Drawings).

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		The '587 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.	ProAir® HFA satisfies this limitation. *See, e.g.*, '587 Patent, 6:38-7:23, Figs. 1-3, 7.

C. U.S. Patent No. 10,861,156 ('156 Patent)

No.	Claim Limitation(s)	Qvar® HFA	ProAir® HFA
1	A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:	Qvar® HFA's inhaler comprises a dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA's inhaler comprises a dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
	a ratchet wheel having a plurality of circumferentially spaced teeth,	Qvar® HFA's inhaler comprises a dose counter with a ratchet wheel having a plurality of circumferentially spaced teeth. *See, e.g.*, TEVAQVAR-00010727,	ProAir® HFA's inhaler comprises a dose counter with a ratchet wheel having a plurality of circumferentially spaced teeth. *See, e.g.*, TEVAQVAR-00066638,

		at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR- 00764096 (Qvar® HFA Design Drawings). The '156 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, 4:34-45, 13:42-15:33, Figs. 10A-10F.	at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings). The '156 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, 4:34-45, 13:42-15:33, Figs. 10A-10F.
	an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,	Qvar® HFA's inhaler comprises a dose counter with an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383,	ProAir® HFA's inhaler comprises a dose counter with an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323,

		at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings). The '156 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, 4:34-45, 13:42-15:33, Figs. 10A-10F.	at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings). The '156 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, 4:34-45, 13:42-15:33, Figs. 10A-10F.
	a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and	Qvar® HFA's inhaler comprises a dose counter with a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085,	ProAir® HFA's inhaler comprises a dose counter with a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313,

		TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
	a dosage indicator associated with the count pawl,	Qvar® HFA's inhaler comprises a dose counter with a dosage indicator associated with the count pawl. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA's inhaler comprises a dose counter with a dosage indicator associated with the count pawl. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
	wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into	Qvar® HFA's inhaler comprises a dose counter wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into	ProAir® HFA's inhaler comprises a dose counter wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into

	engagement with the first tooth,	engagement with the first tooth. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418, at -765419-425, -765649-713 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	engagement with the first tooth. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).

	wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,	Qvar® HFA's inhaler comprises a dose counter wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418, at -765419-425, -765649-713 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA's inhaler comprises a dose counter wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083

			(ProAir® HFA Design Drawings).
	wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.	Qvar® HFA's inhaler comprises a dose counter wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418, at -765419-425, -765649-713 (Qvar® HFA Engineering Qualification Report);	ProAir® HFA's inhaler comprises a dose counter wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307,

		TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings). (Design Drawings).	TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
2	A dose counter as claimed in claim 1	*See* '156 Patent, Claim 1.	*See* '156 Patent, Claim 1.
	in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations.	Qvar® HFA comprises an inhaler in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418, at -765419-425, -765649-713 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR- 00764096 (Qvar® HFA Design	ProAir® HFA comprises an inhaler in which the actuator is displaced less than 1 mm relative to the body between its locations in the canister fire and count configurations. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081,

		Drawings).	TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
9	A dose counter as claimed in claim 1,	*See* '156 Patent, Claim 1.	*See* '156 Patent, Claim 1.
	wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion there between.	Qvar® HFA comprises an inhaler wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion there between. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA comprises an inhaler wherein the count pawl and the ratchet wheel are arranged to permit one way incremental relative motion there between. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
11	An inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as	Qvar® HFA is an inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA	ProAir® HFA is an inhaler comprising the body arranged to retain the medicament canister of predetermined configuration and the dose counter as claimed in claim 1. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir®

	claimed in claim 1.	Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings). *See* '156 Patent, Claim 1.	HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings). *See* '156 Patent, Claim 1.
12	An inhaler as claimed in claim 11	*See* '156 Patent, Claim 11.	*See* '156 Patent, Claim 11.

	in which the body includes a canister- receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister- receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.	Qvar® HFA comprises an inhaler in which the body includes a canister- receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister- receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA comprises an inhaler in which the body includes a canister- receiving portion and a separate counter chamber; the body, ratchet wheel and actuator being located inside the counter chamber, the body of the inhaler having wall surfaces separating the canister- receiving portion and the counter chamber, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
13	The dose counter of claim 1,	*See* '156 Patent, Claim 1.	*See* '156 Patent, Claim 1.

	wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister.	Qvar® HFA comprises an inhaler wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764085, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA comprises an inhaler wherein the shoulder is a bottom surface within the valve stem block and the datum plane is perpendicular to a direction of the movement of the medicament canister. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539312, TEVAQVAR-00539313, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).

D. U.S. Patent No. 10,561,808 ('808 Patent)

No.	Claim Limitation(s)	Qvar® HFA	ProAir® HFA
1	A dose counter for an inhaler, the dose counter having	*See* '156 Patent, Claim 1.	*See* '156 Patent, Claim 1.
	a counter display arranged to indicate dosage information,	Qvar® HFA is an inhaler comprising a counter display to indicate dosage information. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00764079, TEVAQVAR-00764088-TEVAQVAR-00764090, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler comprising a counter display to indicate dosage information. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00539307, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539320, TEVAQVAR-00764079 (Design Drawings).
	a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,	Qvar® HFA is an inhaler comprising a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File);	ProAir® HFA is an inhaler comprising a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File);

		TEVAQVAR-00764074, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings). The '808 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '808 Patent, 2:44-4:50, 8:44-50, 11:35-36, Figs. 8A-8D, claim 2.	TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings). The '808 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, '808 Patent, 2:44-4:50, 8:44-50, 11:35-36, Figs. 8A-8D, claim 2.
	wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.	Qvar® HFA is an inhaler wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements. In Qvar® HFA, this regulator relates to the interaction between a tape stock bobbin and split pin. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764074, TEVAQVAR-00764079,	ProAir® HFA is an inhaler wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements. In ProAir® HFA, this regulator relates to the interaction between a tape stock bobbin and split pin. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539308,

		TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings). The '808 Patent confirms that Qvar® HFA satisfies this limitation. *See, e.g.*, '808 Patent, 2:44-4:50, 17:62-20:11, Figs. 15-20.	TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings). The '808 Patent confirms that ProAir® HFA satisfies this limitation. *See, e.g.*, '808 Patent, 2:44-4:50, 17:62-20:11, Figs. 15-20.
27	The dose counter as claimed in claim 1	*See* '808 Patent, Claim 1.	*See* '808 Patent, Claim 1.
	in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.	Qvar® HFA is an inhaler in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418 (Qvar Engineering Qualification Report); TEVAQVAR-00764074, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design	ProAir® HFA is an inhaler in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081,

		Drawings).	TEVAQVAR-00764083 (ProAir® HFA Design Drawings).
28	The dose counter as claimed in claim 27	*See* '808 Patent, Claim 27.	*See* '808 Patent, Claim 27.
	in which the resistance force is greater than 0.3 N.	Qvar® HFA is an inhaler in which the resistance force is greater than 0.3 N. *See, e.g.*, TEVAQVAR-00010727, at -727, -746-50 (Qvar® HFA Labeling); TEVAQVAR-00008706, at -707-08, -715-16 (Qvar® HFA Container Closure System); TEVAQVAR-00765383, at -393-95 (Qvar® HFA Design History File); TEVAQVAR-00765418 (Qvar® HFA Engineering Qualification Report); TEVAQVAR-00764074, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083, TEVAQVAR-00764088, TEVAQVAR-00764090, TEVAQVAR-00764092, TEVAQVAR-00764096 (Qvar® HFA Design Drawings).	ProAir® HFA is an inhaler in which the resistance force is greater than 0.3 N. *See, e.g.*, TEVAQVAR-00066638, at -648, -660-65 (ProAir® HFA Labeling); TEVAQVAR-00052614, at -615-16, -619-20 (ProAir HFA® Container Closure System); TEVAQVAR-00764323, at -348 (ProAir® HFA Design History File); TEVAQVAR-00761426 (ProAir® HFA Engineering Qualification Report); TEVAQVAR-00539307, TEVAQVAR-00539308, TEVAQVAR-00539316, TEVAQVAR-00539317, TEVAQVAR-00539318, TEVAQVAR-00539319, TEVAQVAR-00539320, TEVAQVAR-00764079, TEVAQVAR-00764081, TEVAQVAR-00764083 (ProAir® HFA Design Drawings).

Exhibit A

David Andrew Lewis BSc MSc PhD
Address: 10 Southerwicks, Corsham, Wiltshire, SN13 9NH, UK
Date of Birth: 6 June 1968

Education:

BSc (Hons) 1989, Physics, University of Essex

MSc 1991, Chemistry, University of Essex, by dissertation: "Spray Characteristics of pressurized packages containing chlorofluorocarbon and hydrocarbon propellant formulations".

PhD 1994, Chemistry, University of Essex, Thesis title: "The evaporation and diffusion of nicotine from mainstream tobacco smoke".

Employment:

17 July 2015 – Present: Director of Oz-UK Limited

Development of inhaled pharmaceutical products. Bespoke research relating to formulation, packaging and design of metered dose inhalers, dry powder inhalers and nebulisers.

7 April 2008 – Present Director of 3DI Solutions Limited

Consultancy for inhaled pharmaceutical products and in-vitro data processing.

01 Aug 2008 – 31 Aug 2020: Director of Aerosol Science, Chiesi Limited, UK (2017-2020)

Head of Laboratory, Chiesi Limited, UK (2008 – 2017)

David joined Chiesi Limited in 2008 and founded the UK Research Centre in Chippenham, UK (Official opening: 9 July 2009). The site was established as the centre of excellence for Chiesi's dry powder inhaler and metered dose inhaler products. During the period 2009-2013 David published 135+ research papers.

In 2014 David founded the bi-annual Research Meeting (Innovation in Inhalation); a one-two day multidisciplinary event with invited internationally recognised speakers. The meeting took place in the UK during 2014, 2016 and 2018 and in Italy during 2019.

In addition, to supervising up to fifteen full-time scientists, David was industrial supervisor for ten PhD students and two post-doc research fellows in collaborations with Bath University, Bristol University, Alberta University, Loughborough University, Sydney University, Monash University, Kings College London, University of Hertfordshire and National Centre for Scientific Research "Demokritos."

07 May 1996 – 01 May 2008: Head of HFA Programmes, Vectura Limited, UK

David joined the Centre for Drug Formulation Studies at Bath University, England, in May 1996 to lead a start-up HFA programme sponsored by Chiesi Farmaceutici. The resultant successful development of HFA solution formulations led to a rapid expansion of his group which transferred to Vectura in 1999 as a result of CDFS spin-out by the University of Bath. During this period, he authored extensive research publications within the fields of pharmaceutics, analytical chemistry, and aerosol science, and was co-inventor of >30 patents relating to pressurized metered dose inhaler formulations and devices. These inventions led to the Chiesi Modulite technology which has seen formulations of beclomethasone dipropionate, budesonide, formoterol and a beclomethasone dipropionate-formoterol combination becoming commercialized in several European countries.

Book Chapters:

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Moderator for explore with the Experts, Tools to facilitate Low GWP Propellant Transition, 2021, Respiratory Drug Delivery Conference 2021

Peer Review Journal Papers:

2. Fernandez M. O., Sweetman D., Stoppacciaro B., Lewis D., Haddrell A. E., Thomas R. J., Buttini F., and Reid J. P., (2022), 'Comparison of Approaches for Measuring the Dissolution Behaviour of Inhaled Dry Powder Formulations', (in Press).
3. Myatt B. J., Versteeg H. K., Hargrave G. K., Long E. J., Gavtash B., Lewis D. A., Church T., Brambilla G., (2022) 'Unlocking further understanding of the atomisation mechanism of a pressurized metered dose inhaler', Aerosol Science & Technology (in Press).
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12. Shur J., Rouse T., Lewis D., Singh D., Morrical B., Edge S., (2018) Defining the Dosage Strength for Labelling of DPIs: Use, Limitations and Relevance of in-vitro Data, Inhalation
13. Tavernini, S., Church T. K., Lewis D. A., Noga M., Martin A.R., Finlay W.H., (2017) 'Deposition of Micrometer-sized Aerosol Particles in Neonatal Nasal Airway Replicas' Aerosol Science and Technology, 52 (4), 407- 419.
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15. Mason-Smith N, Duke DJ, Kastengren AL, Traini D, Young PM, Chen Y, Lewis DA, EdgingtonMitchell D6, Honnery D6.(2017)' Revealing pMDI Spray Initial Conditions: Flashing, Atomisation and the Effect of Ethanol' Pharm Res, Apr: 34(4):718-729.
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R., O'Shea H., Salama R., Traini D. (2014) 'Towards the bioequivalence of pressurised metered dose inhalers 1: design and characterisation of aerodynamically equivalent beclomethasone dipropionate inhalers with and without glycerol as a non-volatile excipient.', Eur. J. Pharm. Biopharm, 86 (1), 31 - 37.

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68. Haddrell, A. E.., Lewis D., Church T., Reid J. P., (2018), 'Directly Probing the Dynamic Behaviour of Particles Originating from DPI and MDI Starting Formulations', Drug Delivery to the Lungs 29
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70. Yeung S., Traini D., Tweedie A., Lewis D., Church T., Young P.M. (2018) 'Aerosol Performance of High Dose Dry Inhalation Dry Powders with Two Dosing Cup Sizes' CRA 2018
71. Haddrell, A. E., Lewis D., Church T., Reid J. P. (2018) 'Directly measuring the rapid evaporation/growth of metered dose inhaler/dry powder inhaler/nebulizer formulations, , 10th International Aerosol Conference, St. Louis. Sept 2 – 7.
72. Terakosolphan W., Malmlöf M., Lewis D., Forbes B., (2017) "The effect of glycerol on the formation of drug particles emitted from solution-based pressurised metered dose inhalers (pMDIs) using different testing apparatus', Drug Delivery to the Lungs 2017
73. Ivey J, Bhambri P, Lewis D, Church T, Finlay W, Vehring R. (2016) 'Dried Corticosteroid Particle Formation from Evaporating Monodisperse Propellant Solution Droplets', AAPS, November 13–17, 2016, Colorado Convention Centre, Denver.
74. Ivey J, Lewis D, Church T, Finlay W, Vehring R, (2016) "Propellant Spray Drying: A Novel, High Throughput, Low Temperature Process for the Production of Respirable Dry Particles", AAPS, November 13–17, 2016, Colorado Convention Centre, Denver.
75. B Myatt, D Lewis, T Church, G Brambilla, GK Hargrave, HK Versteeg, EJ Long, B Gavtash (2015) 'PDA Analysis of HFA/Ethanol pMDI Aerosols: An Improved Test Protocol and New Findings', ICLASS 2015, Tainan, Taiwan, August 23~27, 2015.
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78. Gavtash, B., Myatt, B., O'Shea, H., Mason, F., Lewis, D., Church, T., Versteeg, H.K., Hargrave, G., Brambilla, G. (2015), "Saturated vapour pressure (SVP) measurement of Ethanol/HFA binary mixtures' Drug Delivery to the Lungs 26, pp. 354 – 357.
79. Gavtash, G., Versteeg, H.K., Hargrave, G., Lewis, D., Church, T., Brambilla, G., Myatt, B., O'Shea, H., Mason, F., (2015), 'CFD Simulation of pMDI Aerosols in confined geometry of USP-IP using predictive spray source' Drug Delivery to the Lungs 26, 211 - 214.
80. Tweedie, A., Mason, F., Lewis, D., (2015), 'Investigating the Effect of Modified Breath Actuated Mechanisms on the Dispersion Performance of the NEXThaler®' Drug Delivery to the Lungs 26, 260 - 264.
81. Mason, F., Tweedie, A., Lewis, D., (2015), 'Effect of the Breath-Actuated Mechanism on the Dispersion Performance of the NEXThaler®' Drug Delivery to the Lungs 26, 265 - 269.
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Atomization in a Model System Representing Pressurized Metered Dose Inhaler Sprays', Proc. Respiratory Drug Delivery 2014, Vol 3, 617-620.

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88. Y. Chen, D. Traini, Fletcher D., H. K. Chan, D. Lewis, T. Church, P. M. Young (2013) 'Investigation of nozzle designs and material on the electrostatic charge of pressurised metered dose inhaler ' Drug Delivery to the Lungs 11-13th Dec 2013.
89. Chen Y., Traini D., Fletcher D., Chan H. K., Lewis D., Church T., Young P. M., (2013) 'The effect of pressurised metered dose inhaler (pMDI) actuator orifice geometries on aerosols triboelectrification' Respiratory Drug Delivery 2013 Vol 2, 439-444.
90. Shemirani F.M., Hoe, S., Lewis, D., Church, T., Vehring, R., Finlay, WH. (2013) 'Effect of ambient temperature and humidity on the in vitro regional lung deposition of solution and suspension MDIs' J. Aerosol Med. & Pulm. Drug Del. Vol 26 (2) A35.
91. D. Lewis, H. O'Shea (2012) 'Plume Temperature Measurement of MDIs' Drug Delivery to the Lungs 2012. 5-7th Dec 2012, pp 252 - 256.
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95. Chen Y. Wong W. H. W. Lewis D. Church T. Traini D. Young P. M. (2012) 'Triboelectrification study of a pressurised metered dose inhaler (pMDI) formulation using different actuator materials and orifice designs' Proc. RDD 2012, pp 845 - 850.
96. Shemirani F. M. Mohammad T. Fong J. Azhdarzadeh M. Church T. K. Lewis D. A. Finlay W. H. Vehring R. 'A Continuous, Monodisperse Propellant Microdroplet Stream as a Model System for Laser Analysis of Mass Transfer in MDI Sprays'. RDD 2012 773-776.
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101. Church T. K., Brambilla G., Lewis D. A. and Meakin B. J. (2010), "Effects of Sampling Volume on Drug Delivery from a Metered Dose Inhaler fitted with a Spacer," Proc. Respiratory Drug Delivery XII, pp 513 -516.
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'Formulation of Oestrogens as HFA solution pMDIs'. J. Aerosol med., 16 (2) 211.
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129. Meakin B J; Lewis D A; Ganderton D; and Brambilla G (2000). 'Ipratropium Bromide HFA Solution pMDIs for the treatment of COPD'. Proc. Respiratory Drug Delivery VII, Serentec Press, Raleigh, NC, 369 - 372.
130. Brambilla G; Ganderton D; Lewis D A; Church T K; Meakin B J and Howlett D (1999). 'Through Can Life Variation in Delivered Dose from pMDIs'. 136th British Pharmaceutical Conference and Pharmex, Cardiff.
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Other Refereed Publications:

133. D. Lewis "Extrafine particles and the potential for enhanced inhaled drug delivery" (2016), OINCP, Jan 2017.
134. D. Lewis, A Tweedie (2016), "Enhancing the Performance of Dry Powder Inhalers: Breath Actuated Mechanisms", On Drug Delivery, No 66, 34-38.
135. D. Lewis (2015), "Expert Opinion: Reviewing Current Thinking on the In Vivo Behavior of Particles in the Extra-Fine Region", 1 Dec 2015, 4 - 9.

2012 – 2021: David is Chief Investigator for >AUD$1.2M Australian Research Council funded projects including:

- 2010-2013 ARC-Linkage funding AUS$464,400; Sydney University LP100200156 Dr D Traini; A/Prof PM Young; Prof HK Chan: "Engineering Pressurized Liquid Droplets to Generate High Efficiency Aerosols for Targeted Respiratory Delivery".
- 2012-2015 ARC-Linkage funding $340,000; Sydney University (ARC LP120200744) Prof D Traini; Prof PM Young; Prof D Fletcher: "Ultra-low dose dry powder inhaler technology for the treatment of respiratory diseases".
- 2017-2020 ARC-Linkage Funding AUS$330k Monash University (ARC LP160101845) Prof PM Young; Prof D Honnery; Dr Edgington-Mitchell; Dr David Lewis, "Improving respiratory drug delivery through targeted nozzle design".
- 2018-2021 ARC-Linkage Funding AUS$555k Monash University (ARC LP170100551) Prof Daniela Traini, Prof Julio Soria, Adj/Prof David Fletcher, "Smart hybrid system for the

formulation and design of dry powder inhalers".

Industrial Supervisor (Post-Doctoral Researchers):

2018 - 2020: Industrial Postdoc Researcher "Particle Engineering for Pulmonary Drug Delivery"

- Dr George Kylafis, National Centre for Scientific Research "Demokritos", Athens, Greece: funded Post-Doctoral project with Niarchos Foundation.

2016 - 2020: Postdoc Researcher "Inhalation Aerosol and Response to Humidity"

- Dr Allen Haddrell, Research Fellow, School of Chemistry, Bristol University.

Industrial Supervisor (PhD Studentships):

2010 – 2014: Farzin Molaghasem Shemirani, (PhD) "Metered Dose Inhaler Aerosols: Efficiency, Particle Engineering and Atomization", Department of Mechanical Engineering, University of Alberta.

Deliverables:

- M Azhdarzadeh, F Shemirani, C Ruzycki,A Baldelli, J Ivey, D Barona, T Church, D Lewis, J Olfert, W Finlay, R Vehring. (2016). 'An atomizer to generate monodisperse droplets from high vapor pressure liquids'. J Atom & Sprays, 26 (2) 121-134.
- Shemirani, F. M., Church, T. K., Lewis, D. A., Finlay, W. H., Vehring, R. (2015) Onset of Flash Atomization in a Propellant Micro-jet. Journal of Fluids Engineering, 137, 091101-1 – 0911019.
- Shemirani F.M., Hoe, S., Lewis, D., Church, T., Vehring, R., Finlay, WH. (2013) 'Effect of ambient temperature and humidity on the in vitro regional lung deposition of solution and suspension MDIs' J. Aerosol Med. & Pulm. Drug Del. Vol 26 (2) A35.
- Shemirani F. M.; Hoe S.; Lewis D.; Church T.; Vehring R.; Finlay W. H.; (2012) 'In Vitro Investigation of the Effect of Ambient Humidity on Regional Delivered Dose with Solution and Suspension MDIs' J. Aerosol Med. & Pulm. Drug Del. 26 (0) 1-8
- Shemirani F. M. Mohammad T. Fong J. Azhdarzadeh M. Church T. K. Lewis D. A. Finlay W. H. Vehring R. 'A Continuous, Monodisperse Propellant Microdroplet Stream as a Model System for Laser Analysis of Mass Transfer in MDI Sprays'. RDD 2012 773-776.

2012 – 2015: Yang Chen, (PhD) "The Influence of device and formulation parameters on aerosol electrostatics for pressurised metered dose inhalers", Sydney Medical School, University of Sydney.
Deliverables:

- Chen Y, Young PM, Murphy S, Fletcher DF, Long E, Lewis D, Church T, Traini D (2016) 'High-Speed Laser Image Analysis of Plume Angles for Pressurized Metered Dose Inhalers:
- The Effect of Nozzle Geometry' AAPS PharmSciTech. 17 June 2016.
- Chen Y., Young P.M., Fletcher D., Chan H. K., Long E., Lewis D., Church T., Traini D., (2015) 'The Effect of Active Pharmaceutical Ingredients on Aerosol Electrostatic Charges from Pressurized Metered Dose Inhalers'. J Pharm Res. 32 (9) 2928-36.
- Chen Y., Young P.M., Fletcher D., Chan H. K., Long E., Lewis D., Church T., Traini D., (2014) 'The influence of actuator materials and nozzle designs on electrostatic charge of pressurised metered dose inhaler (pMDI) formulations.' Pharm Res, 31, 1325-1337.
- Chen., Y., Traini, D., Fletcher, D., F., Chan, H., K., Lewis, D., A., Church, T., K., Young, P., M., (2014). 'The Effect of Active Pharmaceutical Ingredients on Aerosols Electrostatic Charges for Pressurised Metered Dose Inhalers', RDD (3) 707-710.
- Chen, Y., Traini, D.,Fletcher D., Chan, H. K., Lewis, D., Church, T., Young P. M., (2013) 'Investigation of nozzle designs and material on the electrostatic charge of pressurised metered dose inhaler ' Drug Delivery to the Lungs 11-13th Dec 2013.
- Chen, Y., Traini, D.,Fletcher D., Chan, H. K., Lewis, D., Church, T., Young P. M., (2013) 'The effect of pressurised metered dose inhaler (pMDI) actuator orifice geometries on aerosols

triboelectrification' Respiratory Drug Delivery 2013 Vol 2, 439-444.

- Chen, Y., Traini, D., Chan, H. K., Lewis, D., Church, T., Young P. M., (2012) 'Investigation of the electrostatic charging effect of different actuator materials and design on pMDI aerosols' Drug Delivery to the Lungs 2012. 5-7th Dec 2012, pp 212 - 215.
- Chen Y. Wong W. H. W. Lewis D. Church T. Traini D. Young P. M. (2012) 'Triboelectrification study of a pressurised metered dose inhaler (pMDI) formulation using different actuator materials and orifice designs' Proc. RDD 2012, pp 845 - 850.

2012 – 2015: Barzin Gavtash, " CFD Simulation of Pressurized Metered Dose Inhaler", Wolfson School of Mechanical and Manufacturing Engineering, Loughborough University.

Deliverables:

- Versteeg H, Hargrave GK, Myatt BJ, Lewis D, Church T, Brambilla G, (2017) Using Phase Doppler Anemometry & High Speed Imaging to Analyze MDI Spray Plume Dynamics (accepted for publication), RDD Europe, Nice.
- B. Gavtash, H. K. Versteeg, G. Hargrave, B. Myatt, D. Lewis, T. Church & G. Brambilla. (online 2017). 'Transient flashing propellant flow models to predict internal flow characteristics, spray velocity, and aerosol droplet size of a pMDI' Aerosol Science and Technology
- B Myatt, D Lewis, T Church, G Brambilla, GK Hargrave, HK Versteeg, EJ Long, B Gavtash (2015) 'PDA Analysis of HFA/Ethanol pMDI Aerosols: An Improved Test Protocol and New Findings', ICLASS 2015, Tainan, Taiwan, August 23~27, 2015.
- Myatt, B., Newton, R., Lewis, D. Church, T., Brambilla, G., Hargrave, G., Versteeg, H., Gavtash, B., Long, E. (2015), "PDA and High Speed Image Analysis of HFA/Ethanol pMDI Aerosols: New Findings' Drug Delivery to the Lungs 26, pp. 74 - 77.
- Gavtash, B., Myatt, B., O'Shea, H., Mason, F., Lewis, D., Church, T., Versteeg, H.K., Hargrave, G., Brambilla, G. (2015), "Saturated vapour pressure (SVP) measurement of Ethanol/HFA binary mixtures' Drug Delivery to the Lungs 26, pp. 354 – 357.
- Gavtash, G., Versteeg, H.K., Hargrave, G., Lewis, D., Church, T., Brambilla, G., Myatt, B., O'Shea, H., Mason, F., (2015), 'CFD Simulation of pMDI Aerosols in confined geometry of USP-IP using predictive spray source' Drug Delivery to the Lungs 26, 211 - 214.
- F Mason, D A Lewis and B.Gavtash. 'Empirical Equations for Predicting the Vapour Pressure of HFA 134a or HFA 227ea Systems containing Ethanol' Drug Delivery to the Lungs 11-13th Dec 2013.

2013 – 2016: Ben Myatt, "A Study of Primary Atomisation and Aerosol Plume Transport of a Pressurised Metered Dose Inhaler", Wolfson School of Mechanical and Manufacturing Engineering, Loughborough University.

Deliverables:

- Versteeg H, Hargrave GK, Myatt BJ, Lewis D, Church T, Brambilla G, (2017) Using Phase Doppler Anemometry & High Speed Imaging to Analyze MDI Spray Plume Dynamics (accepted for publication), RDD Europe, Nice.
- B. Gavtash, H. K. Versteeg, G. Hargrave, B. Myatt, D. Lewis, T. Church & G. Brambilla. (online 2017). 'Transient flashing propellant flow models to predict internal flow characteristics, spray velocity, and aerosol droplet size of a pMDI' Aerosol Science and Technology
- B Myatt, D Lewis, T Church, G Brambilla, GK Hargrave, HK Versteeg, EJ Long, B Gavtash (2015) 'PDA Analysis of HFA/Ethanol pMDI Aerosols: An Improved Test Protocol and New Findings', ICLASS 2015, Tainan, Taiwan, August 23~27, 2015.
- Myatt, B., Newton, R., Lewis, D. Church, T., Brambilla, G., Hargrave, G., Versteeg, H., Gavtash, B., Long, E. (2015), "PDA and High Speed Image Analysis of HFA/Ethanol pMDI Aerosols: New Findings' Drug Delivery to the Lungs 26, pp. 74 - 77.
- Gavtash, B., Myatt, B., O'Shea, H., Mason, F., Lewis, D., Church, T., Versteeg, H.K.,

Hargrave, G., Brambilla, G. (2015), "Saturated vapour pressure (SVP) measurement of Ethanol/HFA binary mixtures' Drug Delivery to the Lungs 26, pp. 354 – 357.

- Gavtash, G., Versteeg, H.K., Hargrave, G., Lewis, D., Church, T., Brambilla, G., Myatt, B., O'Shea, H., Mason, F., (2015), 'CFD Simulation of pMDI Aerosols in confined geometry of USP-IP using predictive spray source' Drug Delivery to the Lungs 26, 211 - 214.

2014 – 2020: Stewart Yeung, "'Limitations of high dose carrier based formulations", Sydney Medical School, University of Sydney.

Deliverables:

- Yeung S., Traini D., Tweedie A., Lewis D., Church T. and Young P.M., (2018) 'Limitations of high dose carrier based formulations. Int. J Pharm; 544(1):141-152.
- Yeung S., Traini D., Tweedie A., Lewis D., Church T. and Young P.M., (2018) 'Dosing challenges in respiratory therapies'. Int. J Pharm; 548(1): 659-671.
- Yeung S., Traini D., Tweedie A., Lewis D., Church T., Young P.M. (2018) 'Aerosol Performance of High Dose Dry Inhalation Dry Powders with Two Dosing Cup Sizes' CRA 2018

2016 – 2020: Nazli Nezami, "A study of factors affecting cavitation and bubble formation in HFA propellants", Wolfson School of Mechanical and Manufacturing Engineering, Loughborough University.

2015 – 2020: Tim Rouse, "To Design and Discover the Perfect Particle for Dry Powder Inhalers" Bath University.

Deliverables:

- Rouse T., Price R., Shur J., Marriner-Edwards C., Lewis D.A., (2017) 'Use Of 3D Printing As A Tool For Fundamental Inhaled Research' AAPS, 12-15 Nov 2017, San Diego Convention Centre

ICASE 4 year post-doctoral programme: 2016 - 2020; "Mechanisms of sugar alcohol effects on respiratory membrane biophysics", awarded in conjunction with Professor Ben Forbes and Dr Richard Harvey at the Institute of Pharmaceutical Science, Kings College London.

2015 – 2020: Precious Akhuemokhan; "The Influence of Non-volatile Excipients on pMDI Aerosol Biopharmaceutics:"

2016 – 2020: Wachirun Terakosolphan; "The influence of non-volatile excipients on pMDI aerosol biopharmaceutics: in vivo studies"

Deliverables:

- Terakosolphan W., Malmlöf M., Lewis D., Forbes B., (2017) "The effect of glycerol on the formation of drug particles emitted from solution-based pressurised metered dose inhalers (pMDIs) using different testing apparatus', Drug Delivery to the Lungs 2017

2015 – 2021: Natalie Armstrong-Green 'Inhalation Aerosol and Response to Humidity', University of Bristol partially funded by the EPSRC Institutional Sponsorship funding

<u>Patents:</u>

135. TNSN98087 (A1), 2000, Pharmaceutical aerosol compositions
136. ITMI991712 (A1), 2001, New pressured metered dose inhalers (MDI) in which all the internal surfaces of the inhalers are stainless steel, anodised aluminium or are lined with an inert organic coating are new
137. ZA200104222 (A), 2002, pressurised metered dose inhalers (mdi)

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